

1/05/00 5:18 pm

Notification Tracking Sheet

=====

Bp number: 00-005-01n

=====

App number: 2000-1XRAB Begin movement: 1/04/00
 Received: 1/05/00 End movement: 1/03/01
 Institution: Monsanto Begin release: 1/04/00
 Recipient: Wheat End release: 1/03/01
 Status: Pending Acre: 2.00
 Effective date: 2/04/00 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (6), (b) (7)(C) [REDACTED]
 Parsed name: (b) (6), (b) (7)(C) [REDACTED] (b) (6), (b) (7)(C) [REDACTED]
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

=====

		Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry		[aip]	[1/6/2000]
2. <input checked="" type="checkbox"/> Review by biotechnologist		[AMK]*	[1/9/2000]
3. <input checked="" type="checkbox"/> Letter of notification to State (fed-ex)		[KLo]	[1/6/2000]*
4. <input type="checkbox"/> State response			

	O/d	Loc	Site	Reg		
Interstate *Dest*CO *				*WR *	[]	[]
Interstate *Dest*KS *				*SCR *	[]	[]
Interstate *Orig*CO *				*WR *		
Interstate *Orig*KS *				*SCR *		
Release * *CO *				1*WR *	[]	[]

5. <input checked="" type="checkbox"/> Enter genes into database		[aip]	[1/6/2000]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw		[KLo]	[1/24/00]*
7. <input checked="" type="checkbox"/> Enter final data into database		[KLo]	[1/24/00]

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-1XRAB

Permit Unit

January 04, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-005-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-1XRAB

3. Applicant/Responsible Party

(b)(6), (b)(7)(c)

Phone

(b)(6), (b)(7)(c)

(b)(6), (b)(7)(c)

FAX

636/737-7085

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EMail

(b)(6), (b)(7)(c)@monsanto.com

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

January 04, 2000 - January 03, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety: Bobwhite and various breeding lines see Appendix A

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Monsanto Reference ID

2000-1XRAB

designation of transformed line: 33391, 33512

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMOVa/12 -- [REDACTED] (b) (4)

CBI

[REDACTED] CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- [REDACTED] (b) (4)
[REDACTED] - CBI

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID

2000-1XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 200 pounds of wheat seed to and from each location.

ORIGIN:

CO, KS

DESTINATION:

CO, KS

Ship From:

CO

(b) (4), Weld County, CO, (b) (4) USA

CONTACT:

(b) (4), CO, (b) (4) USA, (b) (4), (b) (4), (b) (6), (b) (7)(c)

KS

(b) (4), Sedgwick County, KS, (b) (4)

CONTACT:

(b) (4), (b) (4), (b) (6), (b) (7)(c), KS, (b) (4), (b) (6), (b) (7)(c)

Ship To:

CO

(b) (4), Weld County, CO, (b) (4) USA

CONTACT:

(b) (4), (b) (4), (b) (6), (b) (7)(c), CO, (b) (4), (b) (6), (b) (7)(c) USA, (b) (4), (b) (6), (b) (7)(c)

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Monsanto Reference ID

2000-1XRAB

KS

(b) (4), Sedgwick County, KS, (b) (4)

CONTACT: (b)(4), (b)(6), (b)(7)(c), (b)(4), (b)(6), (b)(7) KS, (b)(4), (b)(6), (b)(7)

CONFIDENTIAL

Monsanto Reference ID

2000-1XRAB

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1)

CO

(b)(4), (b)(6), (b)(7)(c), Weld County, CO, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b)(4), (b)(6), (b)(7)(c)
(b)(4), (b)(6), (b)(7)(c), CO, (b)(4), (b)(6), (b)(7)(c) USA, (b)(4), (b)(6), (b)(7)(c)

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Monsanto Reference ID

2000-1XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 04, 2000

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create

essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be

Monsanto ID: 1999-882XRAB

able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-1XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

January 04, 2000

00-005-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-1XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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636/737-7085

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E-Mail

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700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

January 04, 2000 - January 03, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety: Bobwhite and various breeding lines see Appendix A

CBI-DELETED

Monsanto Reference ID

2000-1XRAB

designation of transformed line: 33391, 33512

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2000-1XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 200 pounds of wheat seed to and from each location.

ORIGIN:
CO, KS

DESTINATION:
CO, KS

Ship From:

CO

(b) (4)

, Weld County, CO, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C), CU (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

KS

(b) (4)

, Sedgwick County, KS, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

KS, (b) (4), (b) (6), (b) (7)(C)

Ship To:

CO

(b) (4)

, Weld County, CO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C), CU (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

CBI-DELETED

Monsanto Reference ID
2000-1XRAB

KS

(b) (4)

., Sedgwick County, KS, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

KS, (b) (4), (b) (6), (b) (7)(C)

CBI-DELETED

Monsanto Reference ID

2000-1XRAB

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1)

CO

(b) (4), (b) (6), (b) (7)(C) Weld County, CO, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

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Monsanto Reference ID
2000-1XRAB

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
January 04, 2000

(b) (4)

(b) (4)

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Permit Unit

January 04, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-005-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-1XRAB

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FAX

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EMail

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St. Louis

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Interstate Movement and Release

January 04, 2000 - January 03, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety: Bobwhite and various breeding lines see Appendix A

CBI-DELETED

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2000-1XRAB

designation of transformed line: 33391, 33512

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Monsanto Reference ID

2000-1XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 200 pounds of wheat seed to and from each location.

ORIGIN:
CO, KS

DESTINATION:
CO, KS

Ship From:

CO

(b) (4)

, Weld County, CO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) CU, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

KS

(b) (4)

., Sedgwick County, KS, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)

KS, (b) (4), (b) (6), (b) (7)(C)

Ship To:

CO

(b) (4)

, Weld County, CO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) CU, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

CBI-DELETED

Monsanto Reference ID

2000-1XRAB

KS

(b) (4)

Sedgwick County, KS, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

KS, (b) (4), (b) (6), (b) (7)(C)

CBI-DELETED

Monsanto Reference ID

2000-1XRAB

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1)

CO

(b) (4), (b) (6), (b) (7)(C) Weld County, CO, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)
, CO (b) (4), (b) (6), (b) (7)(C), USA (b) (4), (b) (6), (b) (7)(C)

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9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
January 04, 2000

(b) (4)

(b) (4)

file copy

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

January 5, 2000

Dear Mr. Yergert:

Enclosed is notification 00-005-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-005-01n	Applicant #:	2000-1XRAB
Received:	January 5, 2000	Effective:	February 4, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO KS		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004481

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 5, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-005-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-005-01n	Applicant #:	2000-1XRAB
Received:	January 5, 2000	Effective:	February 4, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO KS		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004482



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

JAN 13 2000

Mr. Mitch Vergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

January 5, 2000

RECEIVED SECTION

Dear Mr. Vergert:

Enclosed is notification 00-005-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-005-01n
Received: January 5, 2000
Institution: Monsanto
Interstate destination: CO KS
Release destination: CO

Applicant #: 2000-1XRAB
Effective: February 4, 2000
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mitchell Vergert

Signature: (b) (6), (b) (7)(C)

Date: January 13, 2000

State: Colorado

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

JAN 13 2000

OR120018_BR_004483



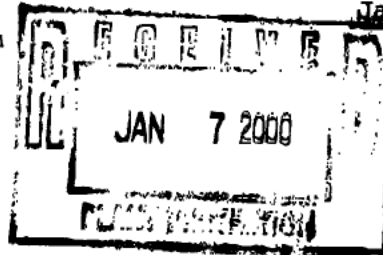
United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Post-it* Fax Note 7671		Date 1/13/00	# of pages 1
To Dianna Autmetor		From Tom Sim	
Co./Dept USDA-		Co. KS Dept. of Agr.	
Phone # 301-734-5787		Phone # 785-862-2180	
Fax # 301-734-8910		Fax # 785-862-0727	

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 5, 2000



Dear Mr. Sim IV:

Enclosed is notification 00-005-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-005-01n
Received: January 5, 2000
Institution: Monsanto
Interstate destination: CO KS
Release destination: CO

Applicant #: 2000-1XRAB
Effective: February 4, 2000
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

~~State concurs with APHIS determination~~

State acknowledges receipt
of this notice.

~~State DOES NOT CONCUR and offers the following reasons:~~

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 1/13/00

State: Kansas

Rptloc01/R4



JAN 13 2000

1/13/00. Dianna said
to treat response
as a concurrence.
fig.

January 24, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C):

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 4, 2000.

Interstate movement and Release
Notification no. 00-005-01n (2000-1XRAB)
Regulated article - Wheat
Destinations - Colorado, Kansas

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO
T. Sim, Kansas State Board of Agric., Topeka, KS
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-005-01n

OR120018_BR_004485

MONSANTO

Food • Health • Hope



August 10, 2000

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

Monsanto's acknowledged wheat notification number 2000-1XRAB,
USDA number 00-005-01n, is requesting the amount of seed be increased
to 1000 pounds.

If you need any further information, please contact me at (b) (6), (b) (7)(C)

Sincerely

(b) (6), (b) (7)(C)

cc:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO
R. Stoaks, PPQ, WR, Sacramento, CA

OR120018_BR_004486

MONSANTO

Food • Health • Hope



August 21, 2000

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Ms. E Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

In reviewing Monsanto's acknowledged wheat notification USDA number 00-005-01n, Monsanto number 2000-1XRAB it was discovered that PV code PV-TXGT12 was omitted. Line number 33512 should be linked to that line. I have enclosed the molecular information that constitutes that PV code.

I apologize for any inconvenience this has caused, if you have any questions,
please phone me at (b) (6), (b) (7)(C)

Sincerely

(b) (6), (b) (7)(C)

Enclosures

OR120018_BR_004487

(b) (4), (b) (6), (b) (7)(C)



2000 Wheat Field Trial Report
USDA # 00-005-01n Monsanto # 2000-1XRAB

(b) (6), (b) (7)(C)

June 8, 2001

Monsanto Company

Location

(b) (4), (b) (6), (b) (7)(C)

County

Weld

State

CO

Weld County, CO

(b) (4)

MONSANTO



August 7, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Ms Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker:

In reviewing Monsanto acknowledged cotton notification, it was discovered a responsible researcher address was incorrectly given. The Monsanto notification is # 2000-735XRAB, USDA # 00-005-01n. The address for (b) (4), (b) (6), (b) (7)(C) should be;

(b) (4)

Department of Entomology and Plant Science

(b) (4)

(b) (4), AL (b) (4)

Lee County

Melanie will move the seed to the release site in Escambia County on the day of release.

If you have any questions, please call at 636/737-6032.

Sincerely,

(b) (6), (b) (7)(C)

cc: S. Wood, USDA, APHIS, PPQ
G. Karr, Alabama Dept. of Agric.

OR120018_BR_004490

MONSANTO



August 10, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Ms Mary Jackson
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms Jackson:

In reviewing Monsanto acknowledged cotton notification, it was discovered a release site address was incorrectly given. The Monsanto notification number is 2000-735XRAB, USDA# [REDACTED] 01n. The release site address should be;

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

, AL

(b) (4), (b) (6), (b) (7)(C)

If you have any questions, please call at 636/737-6032.

Sincerely,

(b) (6), (b) (7)(C)

cc: S. Wood, USDA, APHIS, PPQ
G. Karr, Alabama Dept of Agric.

OR120018_BR_004491

CONFIDENTIAL

2000 Wheat Field Trial Report
USDA # 00-005-01n Monsanto # 2000-1XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location
Site 1

County
Weld

State
CO

Weld County, CO

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-005-01n Monsanto # 2000-1XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Weld	CO

Weld County, CO

Planting Date: February 15, 2000

Harvest Date: August 2, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10 line 33391; PV-TXGT12 line 33512

Purpose of trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

General Results of Field Trial: [CBI deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2/08/00 2:17 pm

Notification Tracking Sheet

=====

Bp number: 00-034-08n

=====

App number: 2000-63XRAB

Received: 2/03/00

Institution: Monsanto

Recipient: Wheat

Status: Pending

Effective date: 3/04/00

Phenotype: HT - Glyphosate tolerant

Comments:

Resp person:

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield, MO 63198

Telephone: (b) (6), (b) (7)(C)

Begin movement: 2/02/00

End movement: 2/01/01

Begin release: 2/02/00

End release: 2/01/01

Acre: 3.00

CBI status: CBI

Fax: 636-737-7085

- | | Initial | Date |
|--|---------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [apb] | [2/2/2000] |
| 2. <input type="checkbox"/> Review by biotechnologist | [Jm]* | []* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KLO] | [2/10/00]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*CO	*	*WR *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Orig*CO	*	*WR *
Interstate	*Orig*MO	*	*SCR *
Release	* *CO	*	1*WR *

[]	[]
[]	[]
[]	[]
[]	[]

- | | | |
|--|---------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [apb] | [2/4/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [KLO] | [2/28/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KLO] | [2/28/00] |

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-63XRAB

Permit Unit

February 02, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-034-08n

1. USDA Reference Number

2. Applicant Reference Number 2000-63XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 02, 2000 - February 01, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite and local Breeding lines.

CONFIDENTIAL

Monsanto Reference ID

2000-63XRAB

designation of transformed line: line 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 --

(b) (4)

CBI

(b) (4) - CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [

(b) (4)

CBI

(b) (4) - CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-63XRAB

designation of transformed line: line 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [(b) (4)]
(b) (4) CBI

CBI

Gene: CTP7-CP4 --

(b) (4)
(b) (4) - CBI

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 --

(b) (4)
(b) (4) - CBI

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)
(b) (4) - CBI

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-63XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1000 pounds of wheat seed to and from each location.

ORIGIN:
CO, MO

DESTINATION:
CO, MO

Ship From:

CO

(b) (4)

Larimer County, CO (b) (4) U.S.A

CONTACT:

(b) (4), (b) (6), (b) (7)(C)
U.S.A, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

CO,

MO

*Monsanto Company, 700 Chesterfield Parkway North, St. Louis, St. Louis County, MO, 63198

CONTACT:

(b) (4), (b) (6), (b) (7)(C)
63198, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) Monsanto Company, 700 Chesterfield Parkway North, St. Louis, MO,

Ship To:

CO

(b) (4)

Larimer County, CO (b) (4) U.S.A

CONFIDENTIAL

Monsanto Reference ID

2000-63XRAB

CONTACT (b) (4), (b) (6), (b) (7)(C) CO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

MO

*Monsanto Company, 700 Chesterfield Parkway North, St. Louis, St. Louis County, MO, 63198

CONTACT (b) (4), (b) (6), (b) (7)(C) Monsanto Company, 700 Chesterfield Parkway North, St. Louis, MO,
63198 (b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-63XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1)

CO

(b) (4) Rio Grande County, CO,
USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-63XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (4), (b) (6), (b) (7)(C)



Monsanto Company

February 02, 2000

OR120018_BR_004503

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-63XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 02, 2000

00-034-08n

1. USDA Reference Number

2. Applicant Reference Number 2000-63XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 02, 2000 - February 01, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite and local Breeding lines.

CBI-DELETED

Monsanto Reference ID

2000-63XRAB

designation of transformed line: line 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-63XRAB

designation of transformed line: line 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-63XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1000 pounds of wheat seed to and from each location.

ORIGIN:
CO, MO

DESTINATION:
CO, MO

Ship From:

CO

(b) (4)

Larimer County, CO, (b) (4) U.S.A

CONTACT:

(b) (4), (b) (6), (b) (7)(C)
U.S.A.

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

CO,

MO

*Monsanto Company, 700 Chesterfield Parkway North, St. Louis, St. Louis County, MO, REDACTED

CONTACT:
63198,

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) Monsanto Company, 700 Chesterfield Parkway North, St. Louis, MO,

Ship To:

CO

(b) (4)

Larimer County, CO, (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-63XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) Fort Collins, CO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

MO

*Monsanto Company, 700 Chesterfield Parkway North, St. Louis, St. Louis County, MO, 63198

CONTACT: (b) (4), (b) (6), (b) (7)(C) Monsanto Company, 700 Chesterfield Parkway North, St. Louis, MO,
63198, (b) (4), (b) (6), (b) (7)(C)

CBI-DELETED

Monsanto Reference ID

2000-63XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

CO (1)

CO

USA, 3 acres.

(b) (4)

, Rio Grande County, CO,

RESPONSIBLE PERSON/RESEARCHER

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) CO, 80523, U.S.A. (b) (4), (b) (6), (b) (7)(C)

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-63XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 02, 2000

OR120018_BR_004513

MONSANTO

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CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID

2000-63XRAB

Permit Unit

February 02, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-034-08n

1. USDA Reference Number

2. Applicant Reference Number 2000-63XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 02, 2000 - February 01, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite and local Breeding lines.

CBI-DELETED

Monsanto Reference ID

2000-63XRAB

designation of transformed line: line 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

EPSPS

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-63XRAB

designation of transformed line: line 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-63XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1000 pounds of wheat seed to and from each location.

ORIGIN:

CO, MO

DESTINATION:

CO, MO

Ship From:

CO

(b) (4)

Larimer County, CO, (b) (4) U.S.A

CONTACT:

(b) (4), (b) (6), (b) (7)(C)
U.S.A

(b) (4), (b) (6), (b) (7)(C)

CO,

MO

*Monsanto Company, 700 Chesterfield Parkway North, St. Louis, St. Louis County, MO, 63198

CONTACT: (b) (4), (b) (6), (b) (7)(C) Monsanto Company, 700 Chesterfield Parkway North, St. Louis, MO,
63198 (b) (4), (b) (6), (b) (7)(C)

Ship To:

CO

(b) (4)

CO, (b) (4) U.S.A

CBI-DELETED

Monsanto Reference ID

2000-63XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

MO

*Monsanto Company, 700 Chesterfield Parkway North, St. Louis, St. Louis County, MO, 63198

CONTACT: (b) (4), (b) (6), (b) (7)(C) Monsanto Company, 700 Chesterfield Parkway North, St. Louis, MO,
63198 (b) (4), (b) (6), (b) (7)(C)

CBI-DELETED

Monsanto Reference ID

2000-63XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1)

CO

(b) (4)

Rio Grande County, CO,

USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) CO,

(b) (4), (b) (6), (b) (7)(C)

U.S.A.,

(b) (4), (b) (6), (b) (7)(C)

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

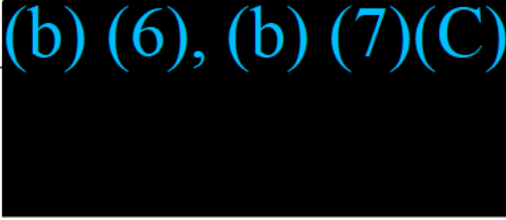
Monsanto Reference ID

2000-63XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 02, 2000

OR120018_BR_004520

file copy

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

February 8, 2000

Dear Mr. Yergert:

Enclosed is notification 00-034-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-034-08n	Applicant #:	2000-63XRAB
Received:	February 3, 2000	Effective:	March 4, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MO		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004521

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 8, 2000

Dear Mr. Brown:

Enclosed is notification 00-034-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-034-08n	Applicant #:	2000-63XRAB
Received:	February 3, 2000	Effective:	March 4, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MO		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004522



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

COPIES 11 PM 12:35

February 8, 2000

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

SECTION

Dear Mr. Yergert:

Enclosed is notification 00-034-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-034-08n	Applicant #:	2000-63XRAB
Received:	February 3, 2000	Effective:	March 4, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MO		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mitchell Yergert

Signature: (b) (6), (b) (7)(C)

Date: 2-16-00

State: Colorado

Rptloc01/R4

RECEIVED BY APHIS - PLANT INDUSTRY DIV. IN LAKEMORE COUNTY



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_004523

FEB 17 2000



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 8, 2000

Dear Mr. Brown:

Enclosed is notification 00-034-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-034-08n	Applicant #:	2000-63XRAB
Received:	February 3, 2000	Effective:	March 4, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MO		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7-CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 2/17/00

State: MO

Rptloc01/R4

FEB 18 2000



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_004524

February 28, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C):

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 4, 2000.

Interstate movement and Release
Notification no. 00-034-08n (2000-63XRAB)
Regulated article - Wheat
Destinations - Colorado, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

In addition, please note on page 6 of this notification that Fort Collins is in Larimer County, not Rio Grande.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
M. Yergert, Colorado Dept. of Agric., Lakewood, CO
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 00-034-08n

OR120018_BR_004525

2000 Wheat Field Trial Report
USDA # 00-034-08n Monsanto # 2000-63XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location
Site 1

County
Rio Grande

State
CO

Rio Grande County, CO – Site 1

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-034-08n Monsanto # 2000-63XRAB

December 7, 2001

Biotech Field Compliance Group
Monsanto Company

Location	County	State
Site 1	Rio Grande	CO

Rio Grande County, CO – Site 1

Planting Date: April 17, 2000

Harvest Date: September 7, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2/08/00 2:17 pm

Notification Tracking Sheet

=====

Bp number: 00-034-09n

=====

App number: 2000-64XRAB
 Received: 2/03/00
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 3/04/00
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

=====

Initial Date

1. ☒ Assign Bp number and initial data entry [*apd*] [2/2/2000]
2. ☐ Review by biotechnologist [*JW*]* []*
3. ☒ Letter of notification to State *Fed-ex* [*KZLO*] [2/10/00]*
4. ☐ State response

O/d	Loc	Site	Reg
Interstate	*Dest*MO	*	*SCR *
Interstate	*Dest*SD	*	*SCR *
Interstate	*Orig*MO	*	*SCR *
Interstate	*Orig*SD	*	*SCR *
Release	* *SD	*	1*SCR *

[] []

[] []

[] []

[] []

[] []

5. ☒ Enter genes into database [*apd*] [2/9/2000]
6. ☒ Letter of acknowledgement/denial/withdraw [*KZLO*] [2/28/00]*
7. ☒ Enter final data into database [*KZLO*] [2/28/00]

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-64XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 02, 2000

00-034-09n

1. USDA Reference Number

2. Applicant Reference Number 2000-64XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

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Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 02, 2000 - February 01, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerate

Cultivar/Variety Bobwhite and Backcross progeny from Bobwhite and Ignor, Oxen, or SD3407

CONFIDENTIAL

Monsanto Reference ID

2000-64XRAB

designation of transformed line: line 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 --

(b) (4)

CBI

(b) (4) - CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 --

(b) (4)

CBI

(b) (4) - CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-64XRAB

designation of transformed line: line 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --
(b) (4) - CBI

(b) (4)

CBI

Gene: CTP2-CP4 --

(b) (4)

CBI

(b) (4)

(b) (4) - CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 --

(b) (4)

CBI

(b) (4)

(b) (4) - CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

CBI

(b) (4)

(b) (4)

- CBI

CONFIDENTIAL

Monsanto Reference ID

2000-64XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1000 pounds of wheat seed to and from each location.

ORIGIN:
MO, SD

DESTINATION:
MO, SD

Ship From:

MO

(b)(4) St. Louis County, MO, (b)(4)

CONTACT: (b)(4), (b)(6), (b)(7)(C) (b)(4) MO,
(b)(4), (b)(6), (b)(7)(C)

SD

(b)(4) Brookings County, SD, (b)(4) U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C) SD, (b)(4), (b)(6), (b)(7)(C)
U.S.A.

Ship To:

MO

(b)(4) St. Louis County, MO, (b)(4)

CONFIDENTIAL

Monsanto Reference ID

2000-64XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) MO,
(b) (4), (b) (6), (b) (7)(C)

SD

(b) (4)

Brookings County, SD (b) (4) U.S.A.

CONTACT:
U.S.A.

(b) (4), (b) (6), (b) (7)(C)

SD, (b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-64XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (1)

SD

(b) (4)

Brookings County, SD, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) S.A.

(b) (4), (b) (6), (b) (7)(C)

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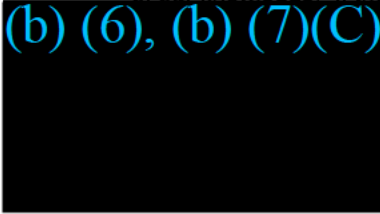
Monsanto Reference ID

2000-64XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 02, 2000

OR120018_BR_004537

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents *for* the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

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CBI-DELETED

MONSANTO COMPANY

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PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-64XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 02, 2000

00-034-09n

1. USDA Reference Number

2. Applicant Reference Number 2000-64XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

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Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 02, 2000 - February 01, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerate

Cultivar/Variety Bobwhite and Backcross progeny from Bobwhite and Ignot, Oxen, or SD3407

CBI-DELETED

Monsanto Reference ID

2000-64XRAB

designation of transformed line: line 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-64XRAB

designation of transformed line: line 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-64XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1000 pounds of wheat seed to and from each location.

ORIGIN:

MO, SD

DESTINATION:

MO, SD

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4)

CONTACT:

(b) (4)

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

MO,

SD

(b) (4)

Brookings County, SD, (b) (4) U.S.A.

CONTACT
U.S.A.

(b) (4), (b) (6), (b) (7)(C)

SD

(b) (4), (b) (6), (b) (7)(C)

Ship To:

MO

(b) (4)

St. Louis County, MO (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-64XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) MO,
(b) (4) (b) (4), (b) (6), (b) (7)(C)

SD

(b) (4)

Brookings County, SD, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C)
U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-64XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (1)

SD

(b) (4)

Brookings County, SD, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER

(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) U.S.A.

(b) (4), (b) (6), (b) (7)(C)

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-64XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 02, 2000

OR120018_BR_004547

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

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Monsanto Reference ID

2000-64XRAB

Permit Unit

February 02, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-034-09n

1. USDA Reference Number

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3. Applicant/Responsible Party

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Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 02, 2000 - February 01, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerate

Cultivar/Variety Bobwhite and Backcross progeny from Bobwhite and Ignor, Oxen, or SD3407

CBI-DELETED

Monsanto Reference ID

2000-64XRAB

designation of transformed line: line 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-64XRAB

designation of transformed line: line 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-64XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1000 pounds of wheat seed to and from each location.

ORIGIN:

MO, SD

DESTINATION:

MO, SD

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

(b) (4)

MO,

SD

(b) (4)

Brookings County, SD, (b) (4) U.S.A.

CONTACT
U.S.A.

(b) (4), (b) (6), (b) (7)(C)

SD

(b) (4), (b) (6), (b) (7)(C)

Ship To:

MO

(b) (4)

St. Louis County, MO, (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-64XRAB

CONTACT- (b) (4), (b) (6), (b) (7)(C) (b) (4) MO,
(b) (4) (b) (4), (b) (6), (b) (7)(C)

SD

(b) (4)

Brookings County, SD, (b) (4) U.S.A.

CONTACT (b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C)
U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-64XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (1)

SD

(b) (4)

Brookings County, SD, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C) U.S.A.

(b) (4), (b) (6), (b) (7)(C)

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-64XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 02, 2000

OR120018_BR_004554

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 8, 2000

Dear Mr. Brown:

Enclosed is notification 00-034-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-034-09n	Applicant #:	2000-64XRAB
Received:	February 3, 2000	Effective:	March 4, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004555

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 8, 2000

Dear Mr. Fridley:

Enclosed is notification 00-034-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-034-09n	Applicant #:	2000-64XRAB
Received:	February 3, 2000	Effective:	March 4, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004556



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 8, 2000

Dear Mr. Brown:

Enclosed is notification 00-034-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-034-09n	Applicant #:	2000-64XRAB
Received:	February 3, 2000	Effective:	March 4, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 2/17/00

State: MO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_004557



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 8, 2000

Dear Mr. Fridley:

Enclosed is notification 00-034-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-034-09n

Received: February 3, 2000

Institution: Monsanto

Interstate destination: MO SD

Release destination: SD

Applicant #: 2000-64XRAB

Effective: March 4, 2000

Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7-CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 2/7/2000

State: South Dakota

Rptloc01/R4



February 28, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 4, 2000.

Interstate movement and Release
Notification no. 00-034-09n (2000-64XRAB)
Regulated article - Wheat
Destinations - Missouri, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-034-09n

OR120018_BR_004559

2000 Wheat Field Trial Report
USDA # 00-034-09n Monsanto # 2000-64XRAB

(b) (6), (b) (7)(C)

June 8, 2000
Monsanto Company

Location
South Dakota State University Farm

County
Brookings

State
SD

Brookings County, SD

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-034-09n Monsanto # 2000-64XRAB

December 7, 2001

Biotech Field Compliance Group
Monsanto Company

Location
Site 1

County
Brookings

State
SD

Brookings County, SD – Site 1

(b) (4)

CONFIDENTIAL

2000 Wheat Field Trial Report
USDA # 00-034-09n Monsanto # 2000-64XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Brookings	SD

Brookings County, SD – Site 1

Planting Date: May 1 and May 3, 2000

Harvest Date: August 4, 2000 and August 14, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

General Results of Field Trial: [CBI deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2/08/00 2:17 pm

Notification Tracking Sheet

=====

Bp number: 00-038-19n

=====

App number: 2000-78XRAB Begin movement: 2/04/00
 Received: 2/07/00 End movement: 2/03/01
 Institution: Monsanto Begin release: 2/04/00
 Recipient: Wheat End release: 2/03/01
 Status: Pending Acre: 6.00
 Effective date: 3/08/00 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person:
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

- | | Initial | Date |
|--|----------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ajd] | [2/9/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [KZL]* | [2/9/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [KZL] | [2/10/00]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg		
Interstate	*Dest*	MO	*	*SCR	*	[]
Interstate	*Dest*	MT	*	*WR	*	[]
Interstate	*Dest*	ND	*	*SCR	*	[]
Interstate	*Orig*	MO	*	*SCR	*	
Interstate	*Orig*	MT	*	*WR	*	
Interstate	*Orig*	ND	*	*SCR	*	
Release	*	MT	*	1*WR	*	[]
Release	*	ND	*	1*SCR	*	[]

- | | | |
|--|---------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [ajd] | [2/9/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [KZL] | [2/28/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KZL] | [2/28/00] |

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-78XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 04, 2000

00-038-19n

1. USDA Reference Number

2. Applicant Reference Number 2000-78XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 04, 2000 - February 03, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite and BW251

CONFIDENTIAL

Monsanto Reference ID

2000-78XRAB

designation of transformed line: line 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- (b) (4)

CBI

(b) (4) - CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- (b) (4)

CBI

(b) (4) - CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-78XRAB

designation of transformed line: line 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 --
(b) (4) CBI

(b) (4)

CBI

Gene: CTP2-CP4 --

(b) (4)

CBI

(b) (4) CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 --

(b) (4)

CBI

(b) (4) CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

CBI

(b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-78XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:
MO, MT, ND

DESTINATION:
MO, MT, ND

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

(b) (4)

MO,

MT

(b) (4)

Yellowstone County, MT, (b) (4)

CONTACT:
MT,

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

ND

(b) (4)

McHenry County, ND, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

ND, (b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-78XRAB

Ship To:

MO

(b) (4)

St. Louis County, MO,

(b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

MO,

(b) (4), (b) (6), (b) (7)(C)

MT

(b) (4)

Yellowstone County, MT,

(b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

MT,

(b) (4), (b) (6), (b) (7)(C)

ND

(b) (4)

McHenry County, ND,

(b) (4)

CONTACT

(b) (4), (b) (6), (b) (7)(C)

ND,

(b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-78XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1), ND (1)

MT

(b) (4)

Yellowstone County, MT, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

MT,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND

(b) (4), (b) (6), (b) (7)(C)

McHenry County, ND, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

ND,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MONSANTO

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

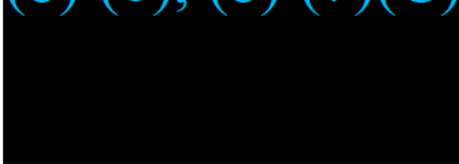
Monsanto Reference ID

2000-78XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 04, 2000

OR120018_BR_004573

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-78XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 04, 2000

00-038-19n

1. USDA Reference Number

2. Applicant Reference Number 2000-78XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 04, 2000 - February 03, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite and BW251

CBI-DELETED

Monsanto Reference ID

2000-78XRAB

designation of transformed line: line 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-78XRAB

designation of transformed line: line 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID
2000-78XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:
MO, MT, ND

DESTINATION:
MO, MT, ND

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4)

CONTACT:

(b) (4)

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

MO,

MT

(b) (4)

Yellowstone County, MT, (b) (4)

CONTACT:

MT,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND

(b) (4)

McHenry County, ND, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

ND (b) (4), (b) (6), (b) (7)(C)

CBI-DELETED

Monsanto Reference ID

2000-78XRAB

Ship To:

MO

(b) (4)

St. Louis County, MO, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

MO,

MT

(b) (4)

Yellowstone County, MT, (b) (4)

CONTACT:

MT, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND

(b) (4)

McHenry County, ND, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

ND,

(b) (4), (b) (6), (b) (7)(C)

CBI-DELETED

Monsanto Reference ID

2000-78XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1), ND (1)

MT

(b) (4)

Yellowstone County, MT, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

ND

(b) (4), (b) (6), (b) (7)(C) McHenry County, ND, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

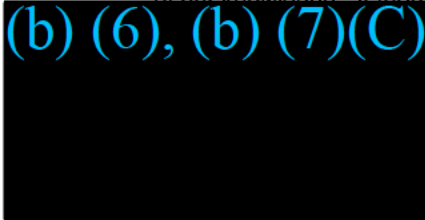
Monsanto Reference ID

2000-78XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 04, 2000

OR120018_BR_004583

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-78XRAB

Permit Unit

February 04, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-038-19n

1. USDA Reference Number

2. Applicant Reference Number 2000-78XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 04, 2000 - February 03, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite and BW251

CBI-DELETED

Monsanto Reference ID

2000-78XRAB

designation of transformed line: line 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-78XRAB

designation of transformed line: line 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID
2000-78XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:
MO, MT, ND

DESTINATION:
MO, MT, ND

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

(b) (4)

St. Louis, MO,

MT

(b) (4)

Yellowstone County, MT, (b) (4)

CONTACT:
MT,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND

(b) (4)

McHenry County, ND, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

ND,

(b) (4), (b) (6), (b) (7)(C)

CBI-DELETED

Monsanto Reference ID

2000-78XRAB

Ship To:

MO

(b) (4)

St. Louis County, MO, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

MO,

(b) (4), (b) (6), (b) (7)(C)

MT

(b) (4)

Yellowstone County, MT, (b) (4)

CONTACT:

MT

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND

(b) (4)

ND, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

ND,

(b) (4), (b) (6), (b) (7)(C)

CBI-DELETED

Monsanto Reference ID

2000-78XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1), ND (1)

MT

(b) (4)

Yellowstone County, MT, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT (b) (4), (b) (6), (b) (7)(C)

ND

(b) (4), (b) (6), (b) (7)(C)

McHenry County, ND, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

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CBI-DELETED

Monsanto Reference ID

2000-78XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of my knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 04, 2000

OR120018_BR_004590

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 8, 2000

Dear Mr. Brown:

Enclosed is notification 00-038-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-038-19n	Applicant #:	2000-78XRAB
Received:	February 7, 2000	Effective:	March 8, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT ND		
Release destination:	MT ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004591

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 8, 2000

Dear Dr. Gingery:

Enclosed is notification 00-038-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-038-19n	Applicant #:	2000-78XRAB
Received:	February 7, 2000	Effective:	March 8, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT ND		
Release destination:	MT ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004592

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 8, 2000

Dear Mr. Nelson:

Enclosed is notification 00-038-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-038-19n	Applicant #:	2000-78XRAB
Received:	February 7, 2000	Effective:	March 8, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT ND		
Release destination:	MT ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004593



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 8, 2000

Dear Mr. Brown:

Enclosed is notification 00-038-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-038-19n	Applicant #:	2000-78XRAB
Received:	February 7, 2000	Effective:	March 8, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT ND		
Release destination:	MT ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E Brown

Signature: (b) (6), (b) (7)(C)

Date: 2/16/00

State: MO

Rptloc01/R4

FEB 18 2000



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_004594



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

[Handwritten signature]

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 8, 2000

Dear Dr. Gingery:

Enclosed is notification 00-038-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-038-19n	Applicant #:	2000-78XRAB
Received:	February 7, 2000	Effective:	March 8, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT ND		
Release destination:	MT ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒

State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Lori M. Witham

Signature:

(b) (6), (b) (7)(C)

Date:

2/16/00

State:

Montana

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 16 2000

OR120018_BR_004595



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 8, 2000

Dear Mr. Nelson:

Enclosed is notification 00-038-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Sp number	00-038-19n	Applicant #:	2000-78XRAB
Received:	February 7, 2000	Effective:	March 8, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT ND		
Release destination:	MT ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

 X State concurs with APHIS determination.

 State DOES NOT CONCUR and offers the following reasons:

Name of State Official: DAVID R. NELSON

Signature: (b) (6), (b) (7)(C)

Date: 2/14/00

State: ND

Rptloc01/R4



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An Equal Opportunity Employer

FEB 15 2000

OR120018_BR_004596

February 28, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 8, 2000.

Interstate movement and Release
Notification no. 00-038-19n (2000-78XRAB)
Regulated article - Wheat
Destinations - Missouri, Montana, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Gingery, Montana Dept. of Agric., Helena, MT
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 00-038-19n

OR120018_BR_004597

2000 Wheat Field Trial Report
USDA # 00-038-19n Monsanto # 2000-78XRAB

May 13, 2001

Biotech Field Compliance Team
Monsanto Company

Location

Site 1

Site 2

County

Yellowstone

McHenry

State

MT

ND

Yellowstone County, MT – Site 1

(b) (4)

McHenry County, ND – Site 2

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

2000 Wheat Field Trial Report
USDA # 00-038-19n Monsanto # 2000-78XRAB

May 13, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Yellowstone	MT
Site 2	McHenry	ND

Yellowstone County, MT – Site 1

Planting Date: May 16, 2000

Harvest Date: August 15, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12 line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

General Results of Field trial: [CBI deleted]

McHenry County, ND – Site 2

Planting Date: May 19, 2000

Harvest Date: August 23, 2000

Destruct Date: September 1, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Final Disposition of Plot Area after Harvesting: [CBI deleted]

CBI-DELETED

General Results of the Field Trial: [CBI deleted]

2000 Wheat Field Trial Report
USDA # 00-038-19n Monsanto # 2000-78XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location
Site 1
Site 2

County
Yellowstone
McHenry

State
MT
ND

Yellowstone County, MT – Site 1

(b) (4)

McHenry County, ND – Site 2

(b) (4)

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-038-19n Monsanto # 2000-78XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Yellowstone	MT
Site 2	McHenry	ND

Yellowstone County, MT – Site 1

Planting Date: May 16, 2000

Harvest Date: August 15, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12 line 33512

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

General Results of Field trial: [CBI deleted]

McHenry County, ND – Site 2

Planting Date: May 19, 2000

Harvest Date: August 23, 2000

Destruct Date: September 1, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Final Disposition of Plot Area after Harvesting: [CBI deleted]

General Results of the Field Trial: [CBI deleted]

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Identification of Items claimed as Confidential Business Information (CBI)

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2/08/00 2:17 pm

Notification Tracking Sheet

=====
Bp number: 00-038-20n
=====

App number: 2000-79XRAB Begin movement: 2/04/00
Received: 2/07/00 End movement: 2/03/01
Institution: Monsanto Begin release: 2/04/00
Recipient: Wheat End release: 2/03/01
Status: Pending Acre: 3.00
Effective date: 3/08/00 CBI status: CBI
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: Hunter, Priscilla E.
Parsed name: Ms. Priscilla E. Hunter Compliance Specialist
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: 636-737-6032 Fax: 636-737-7085
=====

- | | Initial | Date |
|--|-----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>apl</i>] | [2/9/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>KZH</i>]* | [2/9/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KZHO</i>] | [2/10/00]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*MO	*	*SCR *
Interstate	*Dest*ND	*	*SCR *
Interstate	*Orig*MO	*	*SCR *
Interstate	*Orig*ND	*	*SCR *
Release	* *ND	*	1*SCR *

- | | | |
|--|-----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>apl</i>] | [2/9/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KZHO</i>] | [2/28/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KZHO</i>] | [2/28/00] |

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-79XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 04, 2000

00-038-20n

1. USDA Reference Number

2. Applicant Reference Number 2000-79XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 04, 2000 - February 03, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite and Backcross progeny from Bobwhite and local breeding lines.

CONFIDENTIAL

Monsanto Reference ID

2000-79XRAB

designation of transformed line: line 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMeVe/12 (b) (4) (b) (4)

CBI

(b) (4) - CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- (b) (4) (b) (4)

CBI

(b) (4) - CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-79XRAB

designation of transformed line: line 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --
(b) (4) - CBI

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

CBI

(b) (4)

(b) (4) - CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

CBI

(b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-79XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1000 pounds of wheat seed to and from each location.

ORIGIN:
MO, ND

DESTINATION:
MO, ND

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

MO,

(b) (4), (b) (6), (b) (7)(C)

ND

(b) (4)

Cass County, ND, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

ND, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

Ship To:

MO

(b) (4)

St. Louis County, MO, (b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-79XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) MO,
(b) (4), (b) (6), (b) (7)(C)

ND

(b) (4) Cass County, ND, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-79XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

(b) (4)

Cass County, ND, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) ND, 58105, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

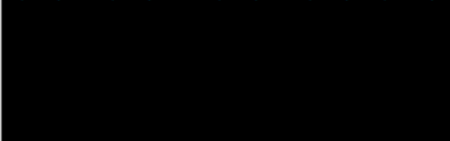
Monsanto Reference ID

2000-79XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 04, 2000

OR120018_BR_004617

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents *for* the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-79XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 04, 2000

00-038-20n

1. USDA Reference Number

2. Applicant Reference Number 2000-79XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 04, 2000 - February 03, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite and Backcross progeny from Bobwhite and local breeding lines.

CBI-DELETED

Monsanto Reference ID

2000-79XRAB

designation of transformed line: line 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-79XRAB

designation of transformed line: line 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-79XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1000 pounds of wheat seed to and from each location.

ORIGIN:
MO, ND

DESTINATION:
MO, ND

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

(b) (4)

St. Louis, MO,

ND

(b) (4)

Cass County, ND, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C)

Ship To:

MO

(b) (4)

St. Louis County, MO, (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-79XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) (b) (4) MO,
(b) (4), (b) (6), (b) (7)(C)

ND

(b) (4)

Cass County, ND, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

CBI-DELETED

Monsanto Reference ID

2000-79XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

(b) (4), (b) (6), (b) (7)(C)

Cass County, ND, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

ND

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-79XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of my knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 04, 2000

OR120018_BR_004627

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-79XRAB

Permit Unit

February 04, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-038-20n

1. USDA Reference Number

2. Applicant Reference Number 2000-79XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 04, 2000 - February 03, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite and Backcross progeny from Bobwhite and local breeding lines.

CBI-DELETED

Monsanto Reference ID

2000-79XRAB

designation of transformed line: line 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-79XRAB

designation of transformed line: line 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-79XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1000 pounds of wheat seed to and from each location.

ORIGIN:
MO, ND

DESTINATION:
MO, ND

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4)

CONTACT:

(b) (4)

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

(b) (4) MO,

ND

(b) (4)

Cass County, ND, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND,

(b) (4), (b) (6), (b) (7)(C)

Ship To:

MO

(b) (4)

St. Louis County, MO, (b) (4)

CBI-DELETED

Monsanto Reference ID
2000-79XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) MO,
(b) (4) (b) (4), (b) (6), (b) (7)(C)

ND

(b) (4)

Cass County, ND, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

CBI-DELETED

Monsanto Reference ID

2000-79XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

(b) (4)

Cass County, ND, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

ND, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

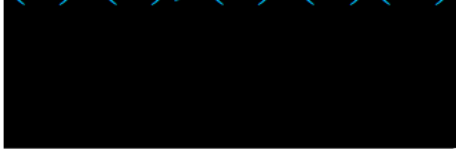
Monsanto Reference ID

2000-79XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 04, 2000

OR120018_BR_004634

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 8, 2000

Dear Mr. Brown:

Enclosed is notification 00-038-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-038-20n	Applicant #:	2000-79XRAB
Received:	February 7, 2000	Effective:	March 8, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004635

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 8, 2000

Dear Mr. Nelson:

Enclosed is notification 00-038-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-038-20n	Applicant #:	2000-79XRAB
Received:	February 7, 2000	Effective:	March 8, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004636



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 8, 2000

Dear Mr. Brown:

Enclosed is notification 00-038-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-038-20n	Applicant #:	2000-79XRAB
Received:	February 7, 2000	Effective:	March 8, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 2/16/00

State: MO

Rptloc01/R4

FEB 18 2000



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An Equal Opportunity Employer

OR120018_BR_004637



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 8, 2000

Dear Mr. Nelson:

Enclosed is notification 00-038-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Sp number	00-038-20n	Applicant #:	2000-79XRAB
Received:	February 7, 2000	Effective:	March 8, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Ratmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: David R. Nelson

Signature: (b) (6), (b) (7)(C)

Date: 2/14/00

State: ND

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 15 2000

OR120018_BR_004638

February 28, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 8, 2000.

Interstate movement and Release
Notification no. 00-038-20n (2000-79XRAB)
Regulated article - Wheat
Destinations - Missouri, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-038-20n

OR120018_BR_004639

2000 Wheat Field Trial Report
USDA # ~~00-038-20n~~ Monsanto # 2000-79XRAB

(b) (6), (b) (7)(C)

June 6, 2001
Monsanto Company

Location
Prosper Research Farm

County
Cass

State
ND

Cass County, ND

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-038-20n Monsanto # 2000-79XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location
Site 1

County
Cass

State
ND

Cass County, ND

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-038-20n Monsanto # 2000-79XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Cass	ND

Cass County, ND

Planting Date: May 17, 2000

Harvest Date: August 21, 2000

Destruct Date: August 25, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, Line 33391; PV-TXGT12, line 33512

Purpose of trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

General Results of Field Trial: [CBI deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

2/08/00 2:17 pm

Notification Tracking Sheet

=====

Bp number: 00-039-05n

=====

App number: 2000-83XRAB
Received: 2/08/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/09/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/07/00
End movement: 2/06/01
Begin release: 2/07/00
End release: 2/06/01
Acre: 15.00
CBI status: CBI

=====

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[aip]	[2/9/2000]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[KLA]*	[2/9/00]*
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[KLA]	[2/10/00]*
4. <input type="checkbox"/> State response		

	O/d	Loc	Site	Reg		
Interstate	*Dest*	KS	*	*SCR	*	[]
Interstate	*Dest*	MT	*	*WR	*	[]
Interstate	*Orig*	KS	*	*SCR	*	[]
Interstate	*Orig*	MT	*	*WR	*	[]
Release	*	*MT	*	3*WR	*	[]

5. <input checked="" type="checkbox"/> Enter genes into database	[aip]	[2/9/2000]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw	[KLA]	[3/9/00]*
7. <input checked="" type="checkbox"/> Enter final data into database	[KLA]	[3/10/00]

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-83XRAB

Permit Unit

February 07, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-039-05n

1. USDA Reference Number

2. Applicant Reference Number 2000-83XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Compliance Specialist

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EEmail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

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Monsanto Reference ID

2000-83XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- (b) (4)
(b) (4) - CBI

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-83XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --
(b) (4) - CBI

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

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Monsanto Reference ID

2000-83XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1220 pound of wheat seed to and from each location.

ORIGIN:

KS, MT

DESTINATION:

KS, MT

Ship From:

KS

(b) (4) Sedgwick County, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) MT, (b) (4) USA, (b) (4), (b) (6), (b) (7)(C)

MT

(b) (4) Cascade County, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) MT, (b) (4) USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4) Pondera County, MT (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) MT, (b) (4) USA, (b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-83XRAB

(b) (4), Hill County, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) MT, (b) (4) USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4) Teton County, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) MT, (b) (4) USA, (b) (4), (b) (6), (b) (7)(C)

Ship To:

KS

(b) (4) Sedgwick County, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) (b) (4) MT, (b) (4) USA, (b) (4), (b) (6), (b) (7)(C)

MT

(b) (4) Cascade County, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) MT, (b) (4) USA, (b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-83XRAB

(b) (4) Pondara County, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) MT, (b) (4) USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4) Hill County, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) MT, (b) (4) USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4) Teton County, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) (b) (4) MT, (b) (4) USA, (b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-83XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (3)

MT

(b) (4)

Pondara County, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)

(b) (4)

MT, (b) (4)

USA (b) (4), (b) (6), (b) (7)(C)

(b) (4)

Hill County, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)

(b) (4)

MT, (b) (4)

USA (b) (4), (b) (6), (b) (7)(C)

(b) (4)

Teton County, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)

(b) (4)

MT, (b) (4)

USA (b) (4), (b) (6), (b) (7)(C)

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PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-83XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 07, 2000

OR120018_BR_004653

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents *for* the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-83XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 07, 2000

00-039-05n

1. USDA Reference Number

2. Applicant Reference Number 2000-83XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-83XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-83XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/l5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-83XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1220 pound of wheat seed to and from each location.

ORIGIN:

KS, MT

DESTINATION:

KS, MT

Ship From:

KS

(b) (4) Sedgwick County, KS, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

MT

(b) (4) Cascade County, MT, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

(b) (4) Pondera County, MT, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-83XRAB

(b) (4), Hill County, MT, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

(b) (4) Teton County, MT, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

Ship To:

KS

(b) (4) Sedgwick County, KS, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

MT

(b) (4) Cascade County, MT, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-83XRAB

(b) (4) Pondara County, MT, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

(b) (4) Hill County, MT, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

(b) (4) Teton County, MT, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-83XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (3)

MT

(b) (4)

Pondara County, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)

USA, (b) (6), (b) (7)(C), (b) (4)

(b) (4)

MT, (b) (4)

(b) (4)

Hill County, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)

USA, (b) (6), (b) (7)(C), (b) (4)

(b) (4)

MT, (b) (4)

(b) (4)

Teton County, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)

USA, (b) (6), (b) (7)(C), (b) (4)

(b) (4)

MT, (b) (4)

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-83XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 07, 2000

OR120018_BR_004664

MONSANTO

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-83XRAB

Permit Unit

February 07, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-039-05n

1. USDA Reference Number

2. Applicant Reference Number 2000-83XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-83XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-83XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-83XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1220 pound of wheat seed to and from each location.

ORIGIN:

KS, MT

DESTINATION:

KS, MT

Ship From:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

MT,

(b) (4)

USA

(b) (6), (b) (7)(C), (b) (4)

MT

(b) (4)

Cascade County, MT, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

MT,

(b) (4)

USA,

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Pondara County, MT, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

MT,

(b) (4)

USA,

(b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID
2000-83XRAB

(b) (4), Hill County, MT, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

(b) (4) Teton County, MT, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) Great Falls, MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

Ship To:

KS

(b) (4) Wichita, Sedgwick County, KS, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

MT

(b) (4) Cascade County, MT, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-83XRAB

(b) (4) Pondara County, MT, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

(b) (4) Hill County, MT, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA (b) (6), (b) (7)(C), (b) (4)

(b) (4) Teton County, MT, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) MT, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-83XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (3)

MT

(b) (4)

Pondara County, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
USA, (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

MT, (b) (4)

(b) (4)

Hill County, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
USA, (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

MT, (b) (4)

(b) (4)

Teton County, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
USA, (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

MT, (b) (4)

MONSANTO

Food • Health • Hope



CBI-DELETED

Monsanto Reference ID

2000-83XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 07, 2000

OR120018_BR_004672

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 8, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-039-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-05n	Applicant #:	2000-83XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004673

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 8, 2000

Dear Dr. Gingery:

Enclosed is notification 00-039-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-05n	Applicant #:	2000-83XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004674



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 8, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-039-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-05n	Applicant #:	2000-83XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7-CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

~~State concurs with APHIS determination.~~

*state cannot evaluate
provided information*

~~State DOES NOT CONCUR and offers the following reasons:~~

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 2/24/00

State: Kansas

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_004675



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 8, 2000

Dear Dr. Gingery:

Enclosed is notification 00-039-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-05n	Applicant #:	2000-83XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7-CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

✓

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Lori M. Witham

Signature:

(b) (6), (b) (7)(C)

Date:

2/16/00

State:

Montana

Rptloc01/R4



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OR120018_BR_004676

FEB 16 2000

March 9, 2000

(b) (6), (b) (7)(C)

Monsanto company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 9, 2000.

Interstate movement and Release
Notification no. 00-039-05n (2000-83XRAB)
Regulated article - Wheat
Destinations - Kansas, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
G. Gingery, Montana Dept. of Agric., Helena, MT
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO

File number 00-039-05n

OR120018_BR_004677

Confirmation Report-Memory Send

Time : Mar-09-00 02:39pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 810
Date : Mar-09 02:38pm
To : 916367377085
Document Pages : 01
Start time : Mar-09 02:38pm
End time : Mar-09 02:39pm
Pages sent : 01
Job number : 810

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 9, 2000

(b) (6), (b) (7)(C)

Monsanto company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 9, 2000.

Interstate movement and Release
Notification no. 00-039-052 (2000-SIXEAB)
Regulated article - Wheat
Destinations - Kansas, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
C. Ginery, Montana Dept. of Agric., Helena, MT
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO



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An Equal Opportunity Employer

OR120018_BR_004678

2000 Wheat Field Trial Report

USDA # 00-039-05n

Monsanto # 2000-83XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Pondera	MT
Site 2	Hill	MT
Site 3	Teton	MT

Pondera County, MT - Site 1

(b) (4)

Pondera County, MT - Site 1

(b) (4)

Hill County, MT - Site 2

(b) (4)

(b) (4)

Teton County, MT - Site 3

(b) (4)

Teton County, MT - Site 3

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2000 Wheat Field Trial Report
USDA # 00-039-05n Monsanto # 2000-83XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Pondera	MT
Site 2	Hill	MT
Site 3	Teton	MT

Pondera County, MT – Site 1

Planting Date: April 28, 2000

Harvest Date: August 24, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Method of Devilitization: [CBI deleted]

General Results of Field Trial: [CBI deleted]

Pondera County, MT – Site 1

Planting Date: April 28, 2000

Harvest Date: August 24, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

General Results of Field Trial: [CBI deleted]

Hill County, MT – Site 2

Planting Date: April 18, 2000

Destruct Date: June 28, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Teton County, MT – Site 3

Planting Date: April 19, 2000

Destruct Date: June 8, 2000 and July 8, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Teton County, MT – Site 3

Planting Date: April 19, 2000

Destruct Date: July 8, 2000 and July 8, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

General Results of Trial: [CBI deleted]

2/08/00 2:17 pm

Notification Tracking Sheet

=====

Bp number: 00-039-06n

=====

App number: 2000-84XRAB
 Received: 2/08/00
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 3/09/00
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: **(b) (6), (b) (7)(C)**
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: **(b) (6), (b) (7)(C)** Fax: 636-737-7085

=====

Initial Date

1. ☒ Assign Bp number and initial data entry [*ajd*] [2/9/2000]
2. ☒ Review by biotechnologist [*KLH*]* [2/9/00]*
3. ☒ Letter of notification to State *Fed-ex* [*KLH*] [2/10/00]*
4. ☐ State response

	O/d	Loc	Site	Reg		
Interstate	*Dest*ID	*		*WR	*	[]
Interstate	*Dest*KS	*		*SCR	*	[]
Interstate	*Dest*WA	*		*WR	*	[]
Interstate	*Orig*ID	*		*WR	*	
Interstate	*Orig*KS	*		*SCR	*	
Interstate	*Orig*WA	*		*WR	*	
Release	*ID	*	2*	WR	*	[]
Release	*WA	*	1*	WR	*	[]

5. ☒ Enter genes into database [*ajd*] [2/9/2000]
6. ☒ Letter of acknowledgement/denial/withdraw [*KLH*] [3/9/00]*
7. ☒ Enter final data into database [*KLH*] [3/10/00]

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-84XRAB

Permit Unit

February 07, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-039-06n

1. USDA Reference Number

2. Applicant Reference Number 2000-84XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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FAX

636/737-7085

E-Mail

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Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

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Monsanto Reference ID

2000-84XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID

2000-84XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- (b) (4) CBI
(b) (4) - CBI

Gene: CTP7-CP4 -- (b) (4) CBI
(b) (4)

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- (b) (4) CBI
(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- (b) (4) CBI
(b) (4)

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Monsanto Reference ID

2000-84XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1220 pounds of wheat seed to and from each location.

ORIGIN:

ID, KS, WA

DESTINATION:

ID, KS, WA

Ship From:

ID

(b) (4)

Latah County, ID, (b) (4) U.S.A.

CONTACT:

(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) U.S.A.,
(b) (4), (b) (6), (b) (7)(C)

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C) (b) (4) Wichita, KS, (b) (4) USA, (b) (4), (b) (6), (b) (7)(C)

WA

(b) (4)

Adams County, WA, USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) U.S.A.,
(b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-84XRAB

Ship To:

ID

(b) (4)

Latah County, ID, (b) (4) U.S.A.

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ID, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

KS, (b) (4) USA

(b) (4), (b) (6), (b) (7)(C)

WA

(b) (4)

Adams County, WA, USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ID, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

CONFIDENTIAL

Monsanto Reference ID

2000-84XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (2), WA (1)

ID

(b) (4)

Latah County, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
ID, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

Latah County, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
ID, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

WA

(b) (4)

Adams County, WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
ID, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-84XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 07, 2000

OR120018_BR_004695

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-84XRAB

Permit Unit

February 07, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-039-06n

1. USDA Reference Number

2. Applicant Reference Number 2000-84XRAB

3. Applicant/Responsible Party

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Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

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Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-84XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-84XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-84XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1220 pounds of wheat seed to and from each location.

ORIGIN:
ID, KS, WA

DESTINATION:
ID, KS, WA

Ship From:

ID

(b) (4) Latah County, ID, (b) (4) J.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) D (b) (4), (b) (6), (b) (7)(C) U.S.A.,
(b) (4), (b) (6), (b) (7)(C)

KS

(b) (4) Sedgwick County, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) KS, (b) (4) USA (b) (4), (b) (6), (b) (7)(C)

WA

(b) (4) Adams County, WA, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID (b) (4), (b) (6), (b) (7)(C) U.S.A.,
(b) (4), (b) (6), (b) (7)(C)

CBI-DELETED

Monsanto Reference ID

2000-84XRAB

Ship To:

ID

(b) (4)

atah County, ID, (b) (4) J.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) U.S.A.,
(b) (4), (b) (6), (b) (7)(C)

KS

(b) (4)

Sedgwick County, KS, 67204, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) KS, (b) (4) USA, (b) (4), (b) (6), (b) (7)(C)

WA

(b) (4)

Adams County, WA, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) S.A.,
(b) (4), (b) (6), (b) (7)(C)

CBI-DELETED

Monsanto Reference ID

2000-84XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (2), WA (1)

ID

(b) (4)

Latah County, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
ID (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

Latah County, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
ID (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

WA

(b) (4)

Adams County, WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
ID (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-84XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 07, 2000

OR120018_BR_004707

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-84XRAB

Permit Unit

February 07, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-039-06n

1. USDA Reference Number

2. Applicant Reference Number 2000-84XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-84XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-84XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-84XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1220 pounds of wheat seed to and from each location.

ORIGIN:

ID, KS, WA

DESTINATION:

ID, KS, WA

Ship From:

ID

(b) (4) Latah County, ID, (b) (4) U.S.A.

CONTACT:

(b) (6), (b) (7)(C), (b) (4) ID (b) (6), (b) (7)(C), (b) (4) U.S.A.,
(b) (6), (b) (7)(C), (b) (4)

KS

(b) (4) Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4) (b) (4) KS, (b) (4) USA (b) (6), (b) (7)(C), (b) (4)

WA

(b) (4) Adams County, WA, USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4) ID (b) (6), (b) (7)(C), (b) (4) U.S.A.,
(b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-84XRAB

Ship To:

ID

(b) (4)

Latah County, ID, (b) (4) U.S.A.

CONTACT:

(b) (6), (b) (7)(C), (b) (4) ID, (b) (6), (b) (7)(C), (b) (4) U.S.A.,
(b) (6), (b) (7)(C), (b) (4)

KS

(b) (4)

Sedgwick County, KS (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4) (b) (4) KS, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

WA

(b) (4)

, Adams County, WA, USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4) (b) (6), (b) (7)(C), (b) (4) D, (b) (6), (b) (7)(C), (b) (4) U.S.A.,
(b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-84XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (2), WA (1)

ID

(b) (4)

Latah County, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
ID, (b) (6), (b) (7)(C), (b) (4) U.S.A., (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Latah County, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
ID, (b) (6), (b) (7)(C), (b) (4) U.S.A., (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

WA

(b) (4)

Adams County, WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
ID, (b) (6), (b) (7)(C), (b) (4) U.S.A., (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-84XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 07, 2000

OR120018_BR_004714

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CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
2000-84XRAB

Permit Unit

February 07, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-039-06n

1. USDA Reference Number

2. Applicant Reference Number 2000-84XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

February 8, 2000

Dear Dr. Vega:

Enclosed is notification 00-039-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-06n	Applicant #:	2000-84XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS WA		
Release destination:	ID WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004716

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 8, 2000

Dear Mr. Wessels:

Enclosed is notification 00-039-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-06n	Applicant #:	2000-84XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS WA		
Release destination:	ID WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004717



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

RECEIVED

FEB 11 2000

PLANT INDUSTRIES

February 8, 2000

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

Dear Dr. Vega:

Enclosed is notification 00-039-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-06n	Applicant #:	2000-84XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS WA		
Release destination:	ID WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: Feb. 11, 2000

State: IDAHO

Rptloc01/R4

FEB 11 2000



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An Equal Opportunity Employer

OR120018_BR_004718



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 8, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-039-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-06n	Applicant #:	2000-84XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS WA		
Release destination:	ID WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7-CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

~~State concurs with APHIS determination.~~

*state cannot evaluate
provided information.*

~~State DOES NOT CONCUR and offers the following reasons:~~

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 2/29/00

State: Kansas

Rptloc01/R4



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OR120018_BR_004719



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 8, 2000

Dear Mr. Wessels:

Enclosed is notification 00-039-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-039-06n Applicant #: 2000-84XRAB
Received: February 8, 2000 Effective: March 9, 2000
Institution: Monsanto Recipient: Wheat
Interstate destination: ID KS WA
Release destination: ID WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/11/00

State: WA

Rptloc01/R4



March 9, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 9, 2000.

Interstate movement and Release
Notification no. 00-039-06n (2000-84XRAB)
Regulated article - Wheat
Destinations - Idaho, Kansas, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

R. Vega, Idaho Dept. of Agric., Boise, ID
T. Sim, Kansas State Board of Agric., Topeka, KS
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-039-06n

OR120018_BR_004721

Confirmation Report-Memory Send

Time : Mar-09-00 02:35pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 805
Date : Mar-09 02:33pm
To : 916367377085
Document Pages : 01
Start time : Mar-09 02:33pm
End time : Mar-09 02:35pm
Pages sent : 01
Job number : 805

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 9, 2000

(b) (6), (b) (7)(C)

700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 9, 2000.

Interstate movement and Release
Notification no. 00-039-06n (2000-84XRAB)
Regulated article - Wheat
Destinations - Idaho, Kansas, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Bachmayer, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
R. Vega, Idaho Dept. of Agric., Boise, ID
T. Sim, Kansas State Board of Agric., Topeka, KS
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO



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An Equal Opportunity Employer

OR120018_BR_004722

2000 Wheat Field Trial Report Draft
USDA # 00-039-06n Monsanto # 2000-84XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Latah	ID
Site 2	Latah	ID
Site 3	Adams	WA

Latah, ID – Site 1

(b) (4)

Latah, ID – Site 2

(b) (4)

(b) (4)

Latah, ID – Site 2

(b) (4)

Adams, WA – Site 3

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2000 Wheat Field Trial Report Draft
USDA # 00-039-06n Monsanto # 2000-84XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Latah	ID
Site 2	Latah	ID
Site 3	Adams	WA

Latah, ID – Site 1

Planting Date: May 5, 2000

Harvest Date: August 29, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT 10 line 33391; PV-TXGT12 line 33512

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

General Results of Trial: [CBI deleted]

Latah, ID – Site 2

Planting Date: May 5, 2000

Destruct Date: July 5, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT 10 line 33391; PV-TXGT12 line 33512

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Latah, ID – Site 2

Planting Date: May 8, 2000

Destruct Date: July 12, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10 line 33391; PV-TXGT12 line 33512

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand:[CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Adams, WA – Site 3

Planting Date: March 31, 2000

Destruct: June 16, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT 10 line 33391, PV-TXGT12 33512

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

2/08/00 2:17 pm

Notification Tracking Sheet

=====
Bp number: 00-039-07n
=====

App number: 2000-85XRAB
Received: 2/08/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/09/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/07/00
End movement: 2/06/01
Begin release: 2/07/00
End release: 2/06/01
Acre: 10.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|-----------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ajd] | [2/9/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [KLD] * | [2/9/00] * |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KLD] | [2/10/00] * |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*	KS	* *SCR *
Interstate	*Dest*	SD	* *SCR *
Interstate	*Orig*	KS	* *SCR *
Interstate	*Orig*	SD	* *SCR *
Release	*	*SD	* 2*SCR *

- | | | |
|--|---------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [ajd] | [2/9/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [KLD] | [3/8/00] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KLD] | [3/8/00] |

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-85XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 07, 2000

00-039-07n

1. USDA Reference Number

2. Applicant Reference Number 2000-85XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

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St. Louis

MO

63198

Phone

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FAX

636/737-7085

EEmail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-85XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-85XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 --

(b) (4)

CBI

(b) (4)

Gene: CTP7-CP4 --

(b) (4)

CBI

(b) (4)

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

CBI

(b) (4)

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Monsanto Reference ID

2000-85XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 10,000 pounds of wheat seed to and from each location.

ORIGIN:
KS, SD

DESTINATION:
KS, SD

Ship From:

KS

* (b) (4) Sedgwick County, KS, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) KS, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

SD

(b) (4) Spink County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) SD, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

(b) (4) Roberts County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) SD, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-85XRAB

(b) (4)

Codington County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4)

(b) (4)

SD, (b) (4) USA,

Ship To:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

KS, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

SD

(b) (4)

Spink County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4)

(b) (4)

SD, (b) (4) USA,

(b) (4)

Roberts County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4)

(b) (4)

SD, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-85XRAB

(b) (4)

Codington County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4)

(b) (4)

SD, (b) (4) USA,

CONFIDENTIAL

Monsanto Reference ID

2000-85XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (2)

SD

(b) (4), (b) (6), (b) (7)(C) Roberts County, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4) (b) (4)
(b) (4) SD, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

(b) (4), (b) (6), (b) (7)(C) Spink County, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4) (b) (4)
(b) (4) SD, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-85XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 07, 2000

OR120018_BR_004738

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents *for* the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

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CBI-DELETED

MONSANTO COMPANY

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<http://www.monsanto.com>

Monsanto Reference ID

2000-85XRAB

Permit Unit

February 07, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-039-0711

1. USDA Reference Number

2. Applicant Reference Number 2000-85XRAB

3. Applicant/Responsible Party

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Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-85XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-85XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-85XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 10,000 pounds of wheat seed to and from each location.

ORIGIN:

KS, SD

DESTINATION:

KS, SD

Ship From:

KS

(b) (4) Sedgwick County, KS, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) KS (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

SD

(b) (4) Spink County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) SD (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

(b) (4) Roberts County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) SD (b) (4) USA (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-85XRAB

* (b) (4) Codington County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) SD, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

Ship To:

KS

(b) (4) Sedgwick County, KS, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) Wichita, KS (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

SD

(b) (4) Spink County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) SD, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

(b) (4) Roberts County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) SD, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-85XRAB

(b) (4)

Codington County, SD (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

SD, (b) (4) USA,

(b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-85XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (2)

SD

(b) (4) Roberts County, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4) (b) (4)
(b) (4) SD, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) Spink County, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4) (b) (4)
(b) (4) SD, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-85XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 07, 2000

OR120018_BR_004749

MONSANTO

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-85XRAB

Permit Unit

February 07, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-039-07n

1. USDA Reference Number

2. Applicant Reference Number 2000-85XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-85XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-85XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-85XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 10,000 pounds of wheat seed to and from each location.

ORIGIN:

KS, SD

DESTINATION:

KS, SD

Ship From:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4)

(b) (4)

Wichita, KS, (b) (4) USA,

(b) (6), (b) (7)(C), (b) (4)

SD

(b) (4)

Spink County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4)

(b) (4)

(b) (4), SD, (b) (4) USA,

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Roberts County, SD, 57279, USA

CONTACT: (b) (6), (b) (7)(C), (b) (4)

(b) (4)

SD, (b) (4) USA

(b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID
2000-85XRAB

(b) (4) Codington County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) SD, (b) (4) USA,

Ship To:

KS

(b) (4) Sedgwick County, KS, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) KS, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

SD

(b) (4) Spink County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) SD, (b) (4) USA,

(b) (4) Roberts County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) SD, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-85XRAB

(b) (4)

Codington County, SD, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

SD, (b) (4) USA,

(b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-85XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (2)

SD

(b) (4) , Roberts County, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)

(b) (4) SD, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

(b) (4)

(b) (6), (b) (7)(C), (b) (4)

Spink County, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)

(b) (4) SD, (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

(b) (4)

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Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-85XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 07, 2000

OR120018_BR_004757

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 8, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-039-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-07n	Applicant #:	2000-85XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004758

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 8, 2000

Dear Mr. Fridley:

Enclosed is notification 00-039-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-07n	Applicant #:	2000-85XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004759



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 8, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-039-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-07n	Applicant #:	2000-85XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

~~State concurs with APHIS determination.~~

*state cannot evaluate
provided information*

~~State DOES NOT CONCUR and offers the following reasons:~~

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 2/24/00

State: Kansas

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_004760



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 8, 2000

Dear Mr. Fridley:

Enclosed is notification 00-039-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-07n	Applicant #:	2000-85XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PFQ, Jefferson City, MO



STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 2/14/2000

State: South Dakota

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_004761

FEB 15 2000

March 8, 2000

(b) (6), (b) (7)(C)

Monsanto company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 9, 2000.

Interstate movement and Release
Notification no. 00-039-07n (2000-85XRAB)
Regulated article - Wheat
Destinations - Kansas, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-039-07n

OR120018_BR_004762

Confirmation Report-Memory Send

Time : Mar-08-00 04:14pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 772
Date : Mar-08 04:13pm
To : 916367377085
Document Pages : 02
Start time : Mar-08 04:13pm
End time : Mar-08 04:14pm
Pages sent : 02
Job number : 772

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 8, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63128

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 9, 2000.

Interstate movement and release
Notification no. 00-039-11a (2000-90XRB)
Regulated article - Wheat
Destinations - Kansas, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hartmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
K. Fritsley, South Dakota Dept. of Agric., Pierre, SD
D. DeWeese, PPQ, SCR, Jefferson City, MO



APHIS - Promoting American Agriculture

An Equal Opportunity Employer

OR120018_BR_004763

2000 Wheat Field Trial Report
USDA # 00-039-07n Monsanto # 2000-085XRAB

(b) (6), (b) (7)(C)

June 6, 2001
Monsanto Company

Location
Sanbokken Farm
Wilson Farm

County
Roberts
Spink

State
SD
SD

Roberts County, SD

(b) (4)

Spink County, SD

(b) (4)

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-039-07n Monsanto # 2000-085XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location

Site 1

Site 2

County

Roberts

Spink

State

SD

SD

Roberts County, SD – Site 1

(b) (4)

Spink County, SD – Site 2

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2000 Wheat Field Trial Report
USDA # 00-039-07n Monsanto # 2000-085XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Roberts	SD
Site 2	Spink	SD

Roberts County, SD – Site 1

Planting Date: April 11 and April 24, 2000

Harvest Date: August 2, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Disposition of the harvested material: [CBI deleted]

Spink County, SD – Site 2

Planting Date: April 12, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33512; PV-TXGT12, line 33391

Purpose of trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

General Results of Field Trial: [CBI deleted]

CBI-DELETED

CONFIDENTIAL

2000 Wheat Field Test Report
USDA #00-039-07n **Monsanto #2000-85XRAB**

AMENDED
December 17, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147303318	Roberts	SD	Not Planted
2147303319	Spink	SD	

Spink County/SD (2147303319)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2000 Wheat Field Test Report
USDA #00-039-07n **Monsanto #2000-85XRAB**

AMENDED
December 17, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147303318	Roberts	SD	Not Planted
2147303319	Spink	SD	

Spink County/SD (2147303319)

Planting Date: 04/12/2000

Harvest Date: 08/02/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

2/08/00 2:17 pm

Notification Tracking Sheet

=====
Bp number: 00-039-09n
=====

App number: 2000-88XRAB Begin movement: 2/07/00
Received: 2/08/00 End movement: 2/06/01
Institution: Monsanto Begin release: 2/07/00
Recipient: Wheat End release: 2/06/01
Status: Pending Acre: 5.00
Effective date: 3/09/00 CBI status: CBI
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)** Fax: 636-737-7085
=====

- | | Initial | Date |
|--|-----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>ajd</i>] | [2/9/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>KLW</i>]* | [2/9/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLW</i>] | [2/10/00]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg		
Interstate	*Dest*	KS	*	*SCR	*	[]
Interstate	*Dest*	WA	*	*WR	*	[]
Interstate	*Orig*	KS	*	*SCR	*	[]
Interstate	*Orig*	WA	*	*WR	*	[]
Release	*	*WA	*	1*WR	*	[]

- | | | |
|--|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>ajd</i>] | [2/9/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KLW</i>] | [3/9/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KLW</i>] | [3/10/00] |

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-88XRAB

Permit Unit

February 07, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-039-09n

1. USDA Reference Number

2. Applicant Reference Number 2000-88XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EEmail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-88XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2000-88XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID
2000-88XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:
KS, WA

DESTINATION:
KS, WA

Ship From:

KS

(b) (4)

Sedgwick County, KS (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

KS (b) (4) USA

(b) (4), (b) (6), (b) (7)(C)

WA

(b) (4)

Whittman County,

WA, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

WA, (b) (4), (b) (6), (b) (7)(C)

USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

Ship To:

KS

(b) (4)

Sedgwick County, KS (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID
2000-88XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4) KS (b) (4) USA (b) (4), (b) (6), (b) (7)(C)

WA
(b) (4)
WA, (b) (4) USA Whittman County,

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, 99164, USA, (b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-88XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b) (4) Whittman County,
WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-88XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 07, 2000

OR120018_BR_004784

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

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CBI-DELETED

MONSANTO COMPANY

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ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-88XRAB

Permit Unit

February 07, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-039-09n

1. USDA Reference Number

2. Applicant Reference Number 2000-88XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-88XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-88XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-88XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:

KS, WA

DESTINATION:

KS, WA

Ship From:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

KS (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

WA

WA, (b) (4) USA

(b) (4)

Whittman County,

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

WA, (b) (6), (b) (7)(C), (b) (4)

USA (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

Ship To:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CBI-DELETED

Monsanto Reference ID

2000-88XRAB

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (4) KS (b) (4) USA (b) (6), (b) (7)(C), (b) (4)

WA

(b) (4) Whitman County,
WA, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) WA (b) (6), (b) (7)(C), (b) (4) USA (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-88XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(k)(1)

Whittman County,

WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

WA,

USA,

(b) (6), (b) (7)(C), (b) (4)

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-88XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 07, 2000

OR120018_BR_004794

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-88XRAB

Permit Unit

February 07, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-039-09n

1. USDA Reference Number

2. Applicant Reference Number 2000-88XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-88XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-88XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID
2000-88XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b) (4)

Whitman County,

WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

WA

(b) (6), (b) (7)(C)

SA,

(b) (6), (b) (7)(C)

MONSANTO

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CBI-DELETED

Monsanto Reference ID

2000-88XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

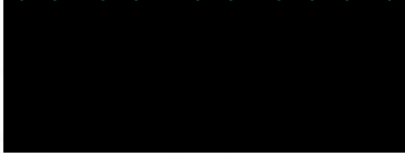
PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 07, 2000

OR120018_BR_004799

CBI-DELETED

Monsanto Reference ID

2000-88XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:

KS, WA

DESTINATION:

KS, WA

Ship From:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C)

(b) (4)

KS, (b) (4) USA

(b) (6), (b) (7)(C)

WA

(b) (4)

Whittman County,

WA, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C) WA, (b) (6), (b) (7)(C) USA, (b) (6), (b) (7)(C)

Ship To:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CBI-DELETED

Monsanto Reference ID
2000-88XRAB

CONTACT: (b) (6), (b) (7)(C) (b) (4) KS, (b) (4) USA (b) (6), (b) (7)(C)

WA

(b) (4)

Whittman County,

WA, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C) WA, (b) (6), (b) (7)(C) USA (b) (6), (b) (7)(C)

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 8, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-039-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-09n	Applicant #:	2000-88XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004802

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 8, 2000

Dear Mr. Wessels:

Enclosed is notification 00-039-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-09n	Applicant #:	2000-88XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004803



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 8, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-039-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-09n	Applicant #:	2000-88XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

~~State concurs with APHIS determination.~~

~~State DOES NOT CONCUR and offers the following reasons:~~

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 2/24/00

State: Kansas

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_004804



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 8, 2000

Dear Mr. Wessels:

Enclosed is notification 00-039-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-09n	Applicant #:	2000-88XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature

(b) (6), (b) (7)(C)

Date: 2/11/00

State: WA

Rptloc01/R4



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An Equal Opportunity Employer

FEB 14 2000

OR120018_BR_004805

March 9, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 9, 2000.

Interstate movement and Release
Notification no. 00-039-09n (2000-88XRAB)
Regulated article - Wheat
Destinations - Kansas, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
T. Wessels, Washington Dept. of Agric., Olympia, WA
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA

File number 00-039-09n

OR120018_BR_004806

2000 Wheat Field Trial Report
USDA # 00-039-09n Monsanto # 2000-88XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location
Site 1

County
Whittman

State
WA

Whittman County, WA – Site 1

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-039-09n Monsanto # 2000-88XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Whittman	WA

Whittman County, WA- Site 1

Planting Date: April 5, 2000

Harvest Date: August 14, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10 line 33391

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Disposition of the harvested material: [CBI deleted]

General Results of Trial: [CBI deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2000 Wheat Field Trial Report

USDA # 00-039-09n

Monsanto # 2000-88XRAB

(b) (6), (b) (7)(C)

June 6, 2001

Monsanto Company

Location

Washington State University

County

Whittman

State

WA

Whittman County, WA

(b) (4)

Confirmation Report-Memory Send

Time : Mar-09-00 02:47pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 815
Date : Mar-09 02:44pm
To : 916367377085
Document Pages : 01
Start time : Mar-09 02:45pm
End time : Mar-09 02:46pm
Pages sent : 01
Job number : 815

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 9, 2000

(b) (6), (b) (7)(C)

Monomanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 9, 2000.

Interstate movement and Release
Notification no. 00-039-09n (2000-SSIRAB)
Regulated article - Wheat
Destinations - Kansas, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

CC:

T. Sim, Kansas State Board of Agric., Topeka, KS
T. Wessels, Washington Dept. of Agric., Olympia, WA
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stroaks, PPQ, WR, Sacramento, CA



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_004812

2/08/00 2:17 pm

Notification Tracking Sheet

=====
Bp number: 00-039-10n
=====

App number: 2000-89XRAB
Received: 2/08/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/09/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)**
Begin movement: 2/07/00
End movement: 2/06/01
Begin release: 2/07/00
End release: 2/06/01
Acre: 5.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|-----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>ajd</i>] | [2/9/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>KLW</i>]* | [2/9/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLW</i>] | [2/10/00]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*KS	*	*SCR *
Interstate	*Dest*WA	*	*WR *
Interstate	*Orig*KS	*	*SCR *
Interstate	*Orig*WA	*	*WR *
Release	*WA	*	1*WR *

- | | | |
|--|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>ajd</i>] | [2/9/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KLW</i>] | [3/9/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KLW</i>] | [3/10/00] |

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-89XRAB

Permit Unit

February 07, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-039-10n

1. USDA Reference Number

2. Applicant Reference Number 2000-89XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Compliance Specialist

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-89XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-89XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- (b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-89XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1220 pounds of wheat seed to and from each location.

ORIGIN:

KS, WA

DESTINATION:

KS, WA

Ship From:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

KS,

(b) (4), (b) (6), (b) (7)(C)

USA,

WA

(b) (4)

Walla Walla County, WA, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

WA,

Ship To:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID

2000-89XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C) USA,

WA

(b) (4) Walla Walla County, WA, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA,
(b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-89XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

WA (1)

WA

(b) (4)

Walla Walla County, WA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C)

MONSANTO

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-89XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (7)(C), (b) (6)

Monsanto Company

February 07, 2000

OR120018_BR_004820

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-89XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 07, 2000

00-039-10n

1. USDA Reference Number

2. Applicant Reference Number 2000-89XRAB

3. Applicant/Responsible Party

(b) (7)(C), (b) (6)

Compliance Specialist

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

Phone

(b) (7)(C), (b) (6)

FAX

636/737-7085

Email

(b) (7)(C), (b) (6)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-89XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-89XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-89XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1220 pounds of wheat seed to and from each location.

ORIGIN:
KS, WA

DESTINATION:
KS, WA

Ship From:

KS

(b) (4) Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4)

KS

(b) (7)(C), (b) (6), (b) (4)

USA,

WA

(b) (4)

Walla Walla County, WA, (b) (4)

CONTACT:

(b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4)

WA,

Ship To:

KS

(b) (4) Sedgwick County, KS, (b) (4) USA

CBI-DELETED

Monsanto Reference ID

2000-89XRAB

CONTACT: (b) (7)(C), (b) (6), (b) (4) KS, (b) (7)(C), (b) (6), (b) (4) USA,

WA

(b) (4)

Walla Walla County, WA, (b) (4)

CONTACT: (b) (7)(C), (b) (6), (b) (4) WA,
(b) (7)(C), (b) (6), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-89XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b) (4)

Walla Walla County, WA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (7)(C), (b) (6), (b) (4)
(b) (7)(C), (b) (6), (b) (4) Walla Walla, WA, (b) (7)(C), (b) (6), (b) (4)

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-89XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (7)(C), (b) (6)

Monsanto Company

February 07, 2000

OR120018_BR_004830

MONSANTO

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-89XRAB

Permit Unit

February 07, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-039-10n

1. USDA Reference Number

2. Applicant Reference Number 2000-89XRAB

3. Applicant/Responsible Party

(b) (7)(C), (b) (6)

Phone

(b) (7)(C), (b) (6)

FAX

636/737-7085

E-Mail

(b) (7)(C), (b) (6)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-89XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-89XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-89XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1220 pounds of wheat seed to and from each location.

ORIGIN:

KS, WA

DESTINATION:

KS, WA

Ship From:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4)

KS

(b) (7)(C), (b) (6), (b) (4)

USA,

WA

(b) (4)

Walla Walla County, WA, (b) (4)

CONTACT:

(b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4)

WA,

Ship To:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CBI-DELETED

Monsanto Reference ID

2000-89XRAB

CONTACT: (b) (7)(C), (b) (6), (b) (4) (b) (7)(C), (b) (6), (b) (4) KS USA,

WA

(b) (4) Nalla Walla County, WA, (b) (4)

CONTACT: (b) (7)(C), (b) (6), (b) (4) (b) (7)(C), (b) (6), (b) (4) WA,

CBI-DELETED

Monsanto Reference ID
2000-89XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b) (4)

Walla Walla County, WA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (7)(C), (b) (6), (b) (4)
(b) (7)(C), (b) (6), (b) (4) WA (b) (7)(C), (b) (6), (b) (4)

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PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-89XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (7)(C), (b) (6)

Monsanto Company

February 07, 2000

OR120018_BR_004837

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 8, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-039-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-10n	Applicant #:	2000-89XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004838

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 8, 2000

Dear Mr. Wessels:

Enclosed is notification 00-039-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-10n	Applicant #:	2000-89XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004839



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 8, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-039-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-10n	Applicant #:	2000-89XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (7)(C), (b) (6)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

*State cannot evaluate
provided information.*

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas Sim IV

Signature: (b) (7)(C), (b) (6)

Date: 2/24/00

State: Kansas

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_004840



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 8, 2000

Dear Mr. Wessels:

Enclosed is notification 00-039-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-039-10n
Received: February 8, 2000
Institution: Monsanto
Interstate destination: KS WA
Release destination: WA

Applicant #: 2000-89XRAB
Effective: March 9, 2000
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (7)(C), (b) (6)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: _____

Date: _____

State: _____

Rptloc01/R4



March 9, 2000

(b) (7)(C), (b) (6)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (7)(C), (b) (6)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 9, 2000.

Interstate movement and Release
Notification no. 00-039-10n (2000-89XRAB)
Regulated article - Wheat
Destinations - Kansas, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
T. Wessels, Washington Dept. of Agric., Olympia, WA
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 00-039-10n

OR120018_BR_004842

Confirmation Report-Memory Send

Time : Mar-09-00 02:47pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 814
Date : Mar-09 02:43pm
To : 916367377085
Document Pages : 01
Start time : Mar-09 02:43pm
End time : Mar-09 02:47pm
Pages sent : 01
Job number : 814

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 9, 2000

(b) (7)(C), (b) (6)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (7)(C), (b) (6)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 9, 2000.

Interstate Movement and Release
Notification no. 00-039-10n (2000-89IKAB)
Regulated article - Wheat
Destinations - Kansas, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (7)(C), (b) (6)

E. Dianne-Hadmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

CC:
T. Sim, Kansas State Board of Agric., Topeka, KS
T. Wessels, Washington Dept. of Agric., Olympia, WA
D. DeWesse, PPQ, SCR, Jefferson City, MO
R. Stoake, PPQ, WR, Sacramento, CA



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_004843

CONFIDENTIAL

2000 Wheat Field Test Report
USDA #00-039-10n **Monsanto #2000-89XRAB**

AMENDED
December 17, 2002

Biotech Field Compliance Team
Monsanto Company

Location
2066639202

County
Walla Walla

State
WA

Walla Walla County/WA (2066639202)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2000 Wheat Field Test Report
USDA #00-039-10n **Monsanto #2000-89XRAB**

AMENDED
December 17, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2066639202	Walla Walla	WA

Walla Walla County/WA (2066639202)

Planting Date: 04/04/2000

Harvest Date: 08/09/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

2/08/00 2:17 pm

Notification Tracking Sheet

=====
Bp number: 00-039-11n
=====

App number: 2000-90XRAB
Received: 2/08/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/09/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/07/00
End movement: 2/06/01
Begin release: 2/07/00
End release: 2/06/01
Acre: 5.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|---|----------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ajd] | [2/9/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [KZD]* | [2/9/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State (Fed-ex) | [KZD] | [2/10/00]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest*	KS	*	*SCR *
Interstate	*Dest*	SD	*	*SCR *
Interstate	*Orig*	KS	*	*SCR *
Interstate	*Orig*	SD	*	*SCR *
Release	*	*SD	*	1*SCR *

- | | | |
|--|---------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [ajd] | [2/9/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [KZD] | [3/8/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KZD] | [3/8/00] |

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-90XRAB

Permit Unit

February 07, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-039-11n

1. USDA Reference Number

2. Applicant Reference Number 2000-90XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

Compliance Specialist

FAX

636/737-7085

Monsanto Company

EEmail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000

- February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-90XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-90XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-90XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:

KS, SD

DESTINATION:

KS, SD

Ship From:

KS

(b) (4)

Sedgwick County, KS (b) (4) ISA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

KS (b) (6), (b) (7)(C), (b) (4)

USA (b) (6), (b) (7)(C), (b) (4)

SD

(b) (4)

Yodington County, SD, (b) (4) ISA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

USA, (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

SD,

(b) (4)

SD, (b) (4), U.S.A

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

U.S.A., (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

SD,

CBI-DELETED

Monsanto Reference ID

2000-90XRAB

Ship To:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

KS,

(b) (6), (b) (7)(C), (b) (4)

USA

(b) (6), (b) (7)(C), (b) (4)

SD

(b) (4)

Codington County, SD, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

USA

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

SD,

(b) (4)

SD, (b) (4) U.S.A

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

U.S.A,

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

SD,

CBI-DELETED

Monsanto Reference ID

2000-90XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (1)

SD

(b) (4)

Codington County, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

USA, (b) (6), (b) (7)(C), (b) (4)

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-90XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 07, 2000

OR120018_BR_004856

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-90XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 07, 2000

00-039-11n

1. USDA Reference Number

2. Applicant Reference Number 2000-90XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C), (b) (4)

Compliance Specialist

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

Phone

(b) (6), (b) (7)(C), (b) (4)

FAX

636/737-7085

EEmail

(b) (6), (b) (7)(C), (b) (4)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2000-90XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-90XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-90XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:

KS, SD

DESTINATION:

KS, SD

Ship From:

KS

(b) (4)

Sedgwick County, KS (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

KS,

(b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4), (b) (6), (b) (7)(C)

SD

(b) (4)

Codington County, SD, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

SD,

(b) (4)

SD,

(b) (4)

U.S.A

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

U.S.A,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

SD,

CONFIDENTIAL

Monsanto Reference ID

2000-90XRAB

Ship To:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

KS,

(b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4), (b) (6), (b) (7)(C)

SD

(b) (4)

Codington County, SD, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

SD,

USA,

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

SD, (b) (4) U.S.A

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

SD,

U.S.A,

(b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-90XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

SD (1)

SD

(b) (4)

Codington County, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-90XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (4), (b) (6), (b) (7)(C)

Monsanto Company

February 07, 2000

OR120018_BR_004863

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-90XRAB

February 07, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-039-11n

1. USDA Reference Number

2. Applicant Reference Number 2000-90XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-90XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-90XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-90XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:

KS, SD

DESTINATION:

KS, SD

Ship From:

KS

(b) (4)

Sedgwick County, KS (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

KS

USA

(b) (6), (b) (7)(C), (b) (4)

SD

(b) (4)

Codington County, SD, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

SD,

USA,

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

SD, (b) (4), U.S.A

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

SD,

U.S.A,

(b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-90XRAB

Ship To:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

KS

(b) (6), (b) (7)(C), (b) (4)

USA

(b) (6), (b) (7)(C), (b) (4)

SD

(b) (4)

Codington County, SD, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

USA,

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

SD,

(b) (4)

SD (b) (4) U.S.A

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

U.S.A,

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

SD,

CBI-DELETED

Monsanto Reference ID

2000-90XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (1)

SD

(b) (4)

Codington County, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER

(b) (6), (b) (7)(C), (b) (4)

SD

(b) (6), (b) (7)(C), (b) (4)

USA

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-90XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 07, 2000

OR120018_BR_004873

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 8, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-039-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-11n	Applicant #:	2000-90XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004874

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 8, 2000

Dear Mr. Fridley:

Enclosed is notification 00-039-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-11n	Applicant #:	2000-90XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004875



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 8, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-039-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-11n	Applicant #:	2000-90XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

*state cannot evaluate
provided information.*

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 2/24/00

State: Kansas

Rptloc01/R4



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OR120018_BR_004876



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 8, 2000

Dear Mr. Fridley:

Enclosed is notification 00-039-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-039-11n	Applicant #:	2000-90XRAB
Received:	February 8, 2000	Effective:	March 9, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 2/14/2000

State: South Dakota

Rptloc01/R4



March 8, 2000

(b) (6), (b) (7)(C)

Monsanto company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C):

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 9, 2000.

Interstate movement and Release
Notification no. 00-039-11n (2000-90XRAB)
Regulated article - Wheat
Destinations - Kansas, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-039-11n

OR120018_BR_004878

Confirmation Report-Memory Send

Time : Mar-08-00 04:14pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 772
Date : Mar-08 04:13pm
To : 916367377085
Document Pages : 02
Start time : Mar-08 04:13pm
End time : Mar-08 04:14pm
Pages sent : 02
Job number : 772

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

March 8, 2000

(b) (6), (b) (7)(C)

Monsanto company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 9, 2000.

Interstate movement and Release
Notification no. 00-039-11n (2000-90XRAB)
Regulated article - Wheat
Destinations - Kansas, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
D. DeWeese, PPQ, SCR, Jefferson City, MO



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An Equal Opportunity Employer

OR120018_BR_004879

2000 Wheat Field Trial Report

USDA # 00-039-11n

Monsanto # 2000-90XRAB

Biotech Field Compliance Team

October 11, 2001

Monsanto Company

Location

Site # 1

County

Codington

State

SD

Site 1

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-039-11n Monsanto # 2000-90XRAB

Biotech Field Compliance Team
October 11, 2001
Monsanto Company

Location
Site # 1

County
Codington

State
SD

Site 1

Planting Date: April 25, 2000

Destruct Dates: Mowed June 22, 2000, Disked July 6, 2001 and Tilled July 7, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, lines 33391

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness Characteristics: [CBI deleted]

Field Monitoring for Plant Stand: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area: [CBI deleted]

Additional Comments: [CBI deleted]

2/10/00 12:17 pm

Notification Tracking Sheet

=====
Bp number: 00-040-05n
=====

App number: 2000-92XRAB
Received: 2/09/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/10/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)**
Begin movement: 2/08/00
End movement: 2/07/01
Begin release: 2/08/00
End release: 2/07/01
Acre: 5.00
CBI status: CBI
Fax: 636-737-7085

=====

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[<i>ajd</i>]	[2/10/2000]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[<i>KLH</i>] *	[2/11/00] *
3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i>	[<i>KLH</i>]	[2/14/00] *
4. <input type="checkbox"/> State response		

	O/d	Loc	Site	Reg		
Interstate	*Dest*	KS	*	*SCR	*	[]
Interstate	*Dest*	OR	*	*WR	*	[]
Interstate	*Orig*	KS	*	*SCR	*	[]
Interstate	*Orig*	OR	*	*WR	*	[]
Release	*	*OR	*	1*WR	*	[]

5. <input type="checkbox"/> Enter genes into database	[]	[]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw	[<i>KLH</i>]	[3/15/00] *
7. <input checked="" type="checkbox"/> Enter final data into database	[<i>KLH</i>]	[3/16/00]

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-92XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 08, 2000

00-040-05n

1. USDA Reference Number

2. Applicant Reference Number 2000-92XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-92XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b) (4)
(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-92XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-92XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:

KS, OR

DESTINATION:

KS, OR

Ship From:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

KS

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

OR

(b) (4)

Umatilla County, OR, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

OR,

Ship To:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID

2000-92XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

OR

(b) (4) Umatilla County, OR, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) OR,
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-92XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OR (1)

OR

(b) (4)

Umatilla County, OR, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

OR,

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

MONSANTO

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-92XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 08, 2000

OR120018_BR_004889

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create

essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be

able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

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PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-92XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 08, 2000

00-040-05n

1. USDA Reference Number

2. Applicant Reference Number 2000-92XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-92XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-92XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-92XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
- 8. Introduction** Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:
KS, OR

DESTINATION:
KS, OR

Ship From:

KS

(b) (4) Sedgwick County, KS (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

KS

(b) (6), (b) (7)(C), (b) (4)

USA

(b) (6), (b) (7)(C), (b) (4)

OR

(b) (4)

Umatilla County, OR (b) (4), USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)
USA

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

OR,

Ship To:

KS

(b) (4)

Sedgwick County, KS (b) (4), USA

CBI-DELETED

Monsanto Reference ID

2000-92XRAB

CONTACT: (b) (6), (b) (7)(C), (b) (4) KS (b) (6), (b) (7)(C), (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

OR

(b) (4)

Umatilla County, OR, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) OR,
(b) (6), (b) (7)(C), (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-92XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OR (1)

OR

(b) (4)

Umatilla County, OR, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4)

OR

(b) (6), (b) (7)(C), (b) (4)

USA,

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

MONSANTO

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-92XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 08, 2000

OR120018_BR_004900

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ST. LOUIS, MISSOURI 63108

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-92XRAB

Permit Unit

February 08, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-040-05n

1. USDA Reference Number

2. Applicant Reference Number 2000-92XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-92XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-92XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-92XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:

KS, OR

DESTINATION:

KS, OR

Ship From:

KS

(b) (4)

Sedgwick County, KS (b) (4), USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

KS

(b) (6), (b) (7)(C), (b) (4)

USA

(b) (6), (b) (7)(C), (b) (4)

OR

(b) (4)

Umatilla County, OR, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

USA

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

OR,

Ship To:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CBI-DELETED

Monsanto Reference ID

2000-92XRAB

CONTACT: (b) (6), (b) (7)(C), (b) (4) KS (b) (6), (b) (7)(C), (b) (4) USA (b) (6), (b) (7)(C), (b) (4)

OR

(b) (4)

Umatilla County, OR, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) OR,
(b) (6), (b) (7)(C), (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-92XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OR (1)

OR

(b) (4)

, Umatilla County, OR, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

OR,

(b) (6), (b) (7)(C), (b) (4)

USA,

(b) (6), (b) (7)(C), (b) (4)

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CBI-DELETED

Monsanto Reference ID

2000-92XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

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PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 08, 2000

OR120018_BR_004907

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 10, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-040-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-05n	Applicant #:	2000-92XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS OR		
Release destination:	OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004908

file copy

Mr. John Griesbach
Oregon Department of Agriculture
Plant Division
635 Capitol St., N.E.
Salem, OR 97310-0110

February 10, 2000

Dear Mr. Griesbach:

Enclosed is notification 00-040-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-05n	Applicant #:	2000-92XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS OR		
Release destination:	OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004909



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281



February 10, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-040-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-05n	Applicant #:	2000-92XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS OR		
Release destination:	OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

~~State concurs with APHIS determination.~~

*State cannot evaluate
information provided.*

~~State DOES NOT CONCUR and offers the following reasons:-~~

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 2/24/00

State: Kansas

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_004910



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

February 10, 2000

Mr. John Griesbach
Oregon Department of Agriculture
Plant Division
635 Capitol St., N.E.
Salem, OR 97310-0110

Dear Mr. Griesbach:

Enclosed is notification 00-040-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-040-05n
Received: February 9, 2000
Institution: Monsanto
Interstate destination: KS OR
Release destination: OR

Applicant #: 2000-92XRAB
Effective: March 10, 2000
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

B. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kathleen J. R. Johnson

Signature: (b) (6), (b) (7)(C)

Date: 3-10-2000

State: Oregon

Rptloc01/R4

MAR 13 2000



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OR120018_BR_004911

March 15, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 15, 2000.

Interstate movement and Release
Notification no. 00-040-05n (2000-92XRAB)
Regulated article - Wheat
Destinations - Kansas, Oregon

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
J. Griesbach, Oregon Dept. of Agric., Salem, OR
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-040-05n

OR120018_BR_004912

Confirmation Report-Memory Send

Time : Mar-15-00 04:57pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 001
Date : Mar-15 04:55pm
To : 916367377085
Document Pages : 01
Start time : Mar-15 04:55pm
End time : Mar-15 04:56pm
Pages sent : 01
Job number : 001

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 15, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 15, 2000.

Interstate Movement and Release
Notification no. 00-040-05n (2000-92XRAB)
Regulated article - Wheat
Destinations - Kansas, Oregon

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

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A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

CC:
T. Sim, Kansas State Board of Agric., Topeka, KS
J. Griesbach, Oregon Dept. of Agric., Salem, OR
R. Starks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-040-05n



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An Equal Opportunity Employer

OR120018_BR_004913

2000 Wheat Field Trial Report
USDA # 00-040-05n Monsanto # 2000-92XRAB

(b) (6), (b) (7)(C)

June 6, 2001
Monsanto Company

Location
Columbia Basin Ag Research Station

County
Umatilla

State
OR

Umatilla County, OR

(b)(4)

CONFIDENTIAL

2000 Wheat Field Trial Report
USDA # 00-040-05n Monsanto # 2000-92XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location
Site 1

County
Umatilla

State
OR

Umatilla County, OR – Site 1

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2000 Wheat Field Trial Report
USDA # 00-040-05n Monsanto # 2000-92XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location
Site 1

County
Umatilla

State
OR

Umatilla County, OR - Site 1

Planting Date: March 31, 2000

Harvest Date: August 7, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

2/10/00 12:17 pm

Notification Tracking Sheet

=====
Bp number: 00-040-06n
=====

App number: 2000-93XRAB Begin movement: 2/08/00
Received: 2/09/00 End movement: 2/07/01
Institution: Monsanto Begin release: 2/08/00
Recipient: Wheat End release: 2/07/01
Status: Pending Acre: 5.00
Effective date: 3/10/00 CBI status: CBI
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)** Fax: 636-737-7085

- =====
- | | Initial | Date |
|--|-----------------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>ajd</i>] | [2/10/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>KLF</i>]* | [2/11/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLW</i>] | [2/14/00]* |
| 4. [] State response | | |

	O/d	Loc	Site	Reg		
Interstate	*Dest*	MO	*	*SCR	*	[]
Interstate	*Dest*	WA	*	*WR	*	[]
Interstate	*Orig*	MO	*	*SCR	*	[]
Interstate	*Orig*	WA	*	*WR	*	[]
Release	*	*WA	*	1*WR	*	[]

5. [] Enter genes into database [] []
6. ☒ Letter of acknowledgement/denial/withdraw [*KLW*] [2/28/00]*
7. ☒ Enter final data into database [*KLW*] [2/28/00]

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-93XRAB

February 08, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-040-06n

1. USDA Reference Number

2. Applicant Reference Number 2000-93XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b)(4)
(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b)(4)
(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [REDACTED]

(b)(4)

(b)(4)

CBI

Gene: CTP7-CP4 -- [REDACTED]

(b)(4)

(b)(4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [REDACTED]

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [REDACTED]

(b)(4)

(b)(4)

CBI

CONFIDENTIAL

Monsanto Reference ID
2000-93XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520, TA S5070, TA S5450,

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- (b)(4)
(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- (b)(4)
(b)(4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/I5 --

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' --

(b)(4)

(b)(4)

(b)(4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 --

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 --

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [Frag

(b)(4)

CBI

(D)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 5000 pounds of wheat seed to and from each location.

ORIGIN:
MO, WA

DESTINATION:
MO, WA

Ship From:

MO

(b)(4)

St. Louis County, MO, (b)(4) U.S.A

CONTACT:

(b)(4), (b)(6), (b)(7)(C)

U.S.A,

(b)(4), (b)(6), (b)(7)(C)

(b)(4), (b)(6), (b)(7)(C)

MO,

WA

(b)(4)

Whittman County, WA, USA

CONTACT:

(b)(4), (b)(6), (b)(7)(C)

WA, USA,

(b)(4), (b)(6), (b)(7)(C)

(b)(4)

Benton County, WA, (b)(4) USA

CONTACT:

(b)(4), (b)(6), (b)(7)(C)

WA,

(b)(4), (b)(6), (b)(7)(C)

USA,

(b)(4), (b)(6), (b)(7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

Ship To:

MO

(b)(4)

St. Louis County, MO (b)(4) U.S.A

CONTACT:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) U.S.A.

MO,

WA

(b)(4)

Whittman County, WA, USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

WA, USA

(b) (4), (b) (6), (b) (7)(C)

(b)(4)

Benton County, WA (b)(4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

WA,

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b)(4)

Whittman County, WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b)(4), (b)(6), (b)(7)(C)

(b)(4), (b)(6), (b)(7)(C) WA, USA,

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-93XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 08, 2000

OR120018_BR_004931

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create

essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be

able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-93XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 08, 2000

00-040-06a

1. USDA Reference Number

2. Applicant Reference Number 2000-93XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520, TA S5070, TA S5450,

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
- 8. Introduction** Interstate Movement and Release

Ship up to 5000 pounds of wheat seed to and from each location.

ORIGIN:
MO, WA

DESTINATION:
MO, WA

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4), U.S.A

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

U.S.A.

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

MO,

WA

(b) (4)

Whittman County, WA, USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

WA, USA

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Benton County, WA, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

WA,

(b) (6), (b) (7)(C), (b) (4)

USA

(b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

Ship To:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A

CONTACT:

63198, U.S.A.,

(b) (6), (b) (7)(C), (b) (4)

MO,

WA

(b) (4)

Whittman County, WA, USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

WA, USA,

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Benton County, WA, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

W,

(b) (6), (b) (7)(C), (b) (4)

USA

(b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b) (4)

Whittman County, WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER (b) (6), (b) (7)(C), (b) (4) WA, USA,
(b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63108

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-93XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 08, 2000

OR120018_BR_004947

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-93XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 08, 2000

00-040-06n

1. USDA Reference Number

2. Applicant Reference Number 2000-93XRAB

3. Applicant/Responsible Party

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MO

63198

Phone

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636/737-7085

EMail

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4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 --

(b) (4)
(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520, TA S5070, TA S5450,

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 --

(b) (4)
(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1.3' --

(b) (4)
(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 5000 pounds of wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

U.S.A,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MO,

WA

(b) (4)

Whittman County, WA, USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

WA, USA,

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

Benton County, WA, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

WA

(b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

Ship To:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

U.S.A,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MO,

WA

(b) (4)

Whittman County, WA, USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

WA, USA

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

Benton County, WA (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

WA,

(b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-93XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b) (4)

Whittman County, WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) WA, USA,

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

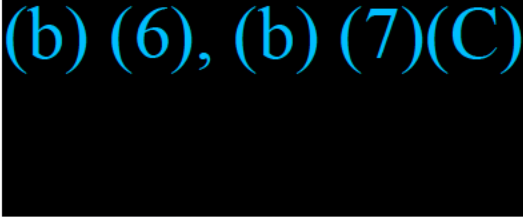
Monsanto Reference ID

2000-93XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 08, 2000

OR120018_BR_004959

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-93XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 08, 2000

00-040-06n

1. USDA Reference Number

2. Applicant Reference Number 2000-93XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520, TA S5070, TA S5450,

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 5000 pounds of wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From:

MO

(b) (4)

St. Louis County, MO (b) (4) U.S.A

CONTACT:

(b) (6), (b) (7)(C), (b) (4) MO,
(b) (6), (b) (7)(C), (b) (4)

WA

(b) (4)

Whittman County, WA, USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) WA, USA (b) (6), (b) (7)(C), (b) (4) D

(b) (4)

Benton County, WA (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) WA, (b) (6), (b) (7)(C), (b) (4) USA (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

Ship To:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

U.S.A.,

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

MO,

WA

(b) (4)

Whittman County, WA, USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

USA

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Benton County, WA, (b) (4) JSA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

WA

(b) (6), (b) (7)(C), (b) (4)

USA

(b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-93XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b) (4) Whittman County, WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER (b) (6), (b) (7)(C), (b) (4) WA, USA,
(b) (6), (b) (7)(C), (b) (4)

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-93XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 08, 2000

OR120018_BR_004971

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create

essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be

able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 10, 2000

Dear Mr. Brown:

Enclosed is notification 00-040-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-06n	Applicant #:	2000-93XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004976

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 10, 2000

Dear Mr. Wessels:

Enclosed is notification 00-040-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-06n	Applicant #:	2000-93XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_004977



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 10, 2000

Dear Mr. Brown:

Enclosed is notification 00-040-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-06n	Applicant #:	2000-93XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

Y

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 2/17/00

State: MO

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_004978

FEB 18 2000



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 10, 2000

Dear Mr. Wessels:

Enclosed is notification 00-040-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-06n	Applicant #:	2000-93XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/15/00

State: WA

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_004979

FEB 15 2000

February 28, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 10, 2000.

Interstate movement and Release
Notification no. 00-040-06n (2000-93XRAB)
Regulated article - Wheat
Destinations - Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 00-040-06n

OR120018_BR_004980

MONSANTO

Food • Health • Hope



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

April 7, 2000

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms Hatmaker;

In reviewing Monsanto's acknowledged wheat notification, it was discovered the release site name was incorrect. USDA number 00-040-06n, Monsanto number 2000-93XRAB, the correct name of the site should be

(b) (6), (b) (7)(C), (b) (4) Whitman County.

I apologize for any inconvenience this may cause. Please call me at 636/737-6032 if you have any questions.

Sincerely

(b) (6), (b) (7)(C)

cc:

(b) (6), (b) (7)(C)

WA

R. Stokes, Regional Biotechnologist, Sacramento, CA

OR120018_BR_004981

2000 Wheat Field Trial Report
USDA # 00-040-06n Monsanto # 2000-93XRAB

(b) (6), (b) (7)(C)

June 6, 2001
Monsanto Company

Location
Bob Druffel Farm

County
Whitman

State
WA

Whitman County, WA

(b) (4)

CONFIDENTIAL

2000 Wheat Field Trial Report

USDA # 00-040-06n

Monsanto # 2000-93XRAB

December 7, 2001

**Biotech Field Compliance Team
Monsanto Company**

**Location
Site 1**

**County
Whitman**

**State
WA**

Whitman County, WA- Site 1

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2000 Wheat Field Trial Report
USDA # 00-040-06n Monsanto # 2000-93XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location
Site 1

County
Whitman

State
WA

Whitman County, WA- Site 1

Planting Date: April 11, 2000

Harvest Date: August 25, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512.

Purpose of trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI deleted]

Field Monitoring Observations for Plant Stand: [CBI deleted]

Disposition of the Harvested Material: [The harvested grain was buried at the release site.] - CBI

General Results of Field trial: [CBI deleted]

=====

Bp number: 00-040-09n

=====

App number: 2000-97XRAB
 Received: 2/09/00
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 3/10/00
 Phenotype: HT - Glyphosate tolerant

Begin movement: 2/08/00
 End movement: 2/07/01
 Begin release: 2/08/00
 End release: 2/07/01
 Acre: 20.00
 CBI status: CBI

Comments:

Resp person:

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield, MO 63198

Telephone: (b) (6), (b) (7)(C)

Fax: 636-737-7085

Initial

Date

1. ☒ Assign Bp number and initial data entry

[*aid*]

[2/10/2000]

2. ☒ Review by biotechnologist

[*LMK*]*

[2/11/2000]*

3. ☒ Letter of notification to State *Fed-ex*

[*KLO*]

[2/14/00]*

4. ☐ State response

	O/d	Loc	Site	Reg
Interstate	*Dest*	KS	*	*SCR *
Interstate	*Dest*	OR	*	*WR *
Interstate	*Dest*	WA	*	*WR *
Interstate	*Orig*	KS	*	*SCR *
Interstate	*Orig*	OR	*	*WR *
Interstate	*Orig*	WA	*	*WR *
Release	*	*OR	*	2*WR *
Release	*	*WA	*	2*WR *

[]	[]	[]	[]
[]	[]	[]	[]
[]	[]	[]	[]

[]	[]	[]	[]
[]	[]	[]	[]

5. ☐ Enter genes into database

[] [] [] []

6. ☒ Letter of acknowledgement/denial/withdraw

[*KLO*]

[3/15/00]*

7. ☒ Enter final data into database

[*KLO*]

[3/14/00]

*Asked Priscilla
 to correct
 the M1
 terminator
 description.*

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CONFIDENTIAL

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700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

http://www.monsanto.com

Monsanto Reference ID

2000-97XRAB

Permit Unit

February 08, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-040-09n

1. USDA Reference Number

2. Applicant Reference Number 2000-97XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2000-97XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID
2000-97XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

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Monsanto Reference ID
2000-97XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 5000 pounds of wheat seed to and from each location.

ORIGIN:
KS, OR, WA

DESTINATION:
KS, OR, WA

Ship From:

KS

(b) (4) Sedgwick County, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) Wichita, KS, (b) (4), (b) (6), (b) (7)(C) USA

OR

(b) (4), (b) (6), (b) (7)(C) Morrow County, OR, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) Wichita, KS, (b) (4), (b) (6), (b) (7)(C) USA

(b) (4), (b) (6), (b) (7)(C) Umatilla County, OR, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA

CONFIDENTIAL

Monsanto Reference ID
2000-97XRAB

WA

(b) (4)

Whittman County, WA, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4)

Lincoln County, WA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA

(b) (4)

Benton County, WA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

Ship To:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA

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Monsanto Reference ID
2000-97XRAB

OR

(b) (4), (b) (6), (b) (7)(C) Morrow County, OR (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C) USA

(b) (4), (b) (6), (b) (7)(C) Umatilla County, OR, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C) USA

WA

(b) (4) Whittman County, WA, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, USA (b) (4), (b) (6), (b) (7)(C)

(b) (4) Lincoln County, WA (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) , KS (b) (4), (b) (6), (b) (7)(C) USA

CONFIDENTIAL

Monsanto Reference ID
2000-97XRAB

(b) (4)

Benton County, WA, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-97XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OR (2), WA (2)

OR

(b) (4), (b) (6), (b) (7)(C) Morrow County, OR, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

WA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) Umatilla County, OR, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

WA, (b) (4), (b) (6), (b) (7)(C)

WA

(b) (4) Lincoln County, WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

WA, (b) (4), (b) (6), (b) (7)(C)

(b) (4) Whitman County, WA, USA, 5 acres.

CONFIDENTIAL

Monsanto Reference ID
2000-97XRAB

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

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700 CHESTERFIELD PARKWAY NORTH
St. Louis, Missouri 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-97XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (7)(C), (b) (6)



Monsanto Company

February 08, 2000

OR120018_BR_004997

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create

essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be

able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, “[]”, as labeled as CBI.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-97XRAB

Permit Unit

February 08, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-040-09n

1. USDA Reference Number

2. Applicant Reference Number 2000-97XRAB

3. Applicant/Responsible Party

(b) (7)(C), (b) (6)

Phone

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636/737-7085

Email

(b) (7)(C), (b) (6)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-97XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-97XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID
2000-97XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 5000 pounds of wheat seed to and from each location.

ORIGIN:
KS, OR, WA

DESTINATION:
KS, OR, WA

Ship From:

KS

(b) (4) Sedgwick County, KS, (b) (4) USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) KS, (b) (7)(C), (b) (6), (b) (4) USA

OR

(b) (7)(C), (b) (6), (b) (4) Morrow County, OR, (b) (7)(C), (b) (6), (b) (4) USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) KS, (b) (7)(C), (b) (6), (b) (4) USA

(b) (7)(C), (b) (6), (b) (4) Jmatilla County, OR, (b) (7)(C), (b) (6), (b) (4) USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) KS, (b) (7)(C), (b) (6), (b) (4) USA

CBI-DELETED

Monsanto Reference ID
2000-97XRAB

WA
(b) (4) Whittman County, WA, USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) WA, USA (b) (7)(C), (b) (6), (b) (4)

(b) (4) Lincoln County, WA, (b) (4) USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) KS (b) (7)(C), (b) (6), (b) (4) USA

(b) (4) Benton County, WA, (b) (4) USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) WA (b) (7)(C), (b) (6), (b) (4) USA (b) (7)(C), (b) (6), (b) (4)

Ship To:

KS
(b) (4) Sedgwick County, KS, (b) (4) USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) KS (b) (7)(C), (b) (6), (b) (4) USA

CBI-DELETED

Monsanto Reference ID
2000-97XRAB

OR

(b) (7)(C), (b) (6), (b) (4) Morrow County, OR (b) (7)(C), (b) (6), (b) (4) USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) KS (b) (7)(C), (b) (6), (b) (4) USA

(b) (7)(C), (b) (6), (b) (4) Umatilla County, OR (b) (7)(C), (b) (6), (b) (4) USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) KS (b) (7)(C), (b) (6), (b) (4) USA

WA

(b) (4) Whittman County, WA, USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) WA, USA, (b) (7)(C), (b) (6), (b) (4)

(b) (4) Lincoln County, WA, (b) (4) USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) KS (b) (7)(C), (b) (6), (b) (4) USA

CBI-DELETED

Monsanto Reference ID
2000-97XRAB

(b) (4) Benton County, WA, (b) (4) JSA

CONTACT: (b) (7)(C), (b) (6), (b) (4) USA (b) (7)(C), (b) (6), (b) (4)

CBI-DELETED

Monsanto Reference ID
2000-97XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OR (2), WA (2)

OR

(b) (7)(C), (b) (6), (b) (4)

Morrow County, OR, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
USA, (b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4)

WA, (b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4)

Umatilla County, OR, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
USA, (b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4)

WA, (b) (7)(C), (b) (6), (b) (4)

WA

(b) (4)

Lincoln County, WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
USA, (b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4)

WA, (b) (7)(C), (b) (6), (b) (4)

(b) (4)

Whitman County, WA, USA, 5 acres.

CBI-DELETED

Monsanto Reference ID
2000-97XRAB

RESPONSIBLE PERSON/RESEARCHER: (b) (7)(C), (b) (6), (b) (4) WA, (b) (7)(C), (b) (6), (b) (4)
USA (b) (7)(C), (b) (6), (b) (4)

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>


Monsanto Reference ID

2000-97XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (7)(C), (b) (6)



Monsanto Company

February 08, 2000

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<http://www.monsanto.com>

Monsanto Reference ID

2000-97XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 08, 2000

00-040-09n

1. USDA Reference Number

2. Applicant Reference Number 2000-97XRAB

3. Applicant/Responsible Party

(b) (7)(C), (b) (6)

Phone

(b) (7)(C), (b) (6)

FAX

636/737-7085

E-Mail

(b) (7)(C), (b) (6)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-97XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-97XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID
2000-97XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 5000 pounds of wheat seed to and from each location.

ORIGIN:
KS, OR, WA

DESTINATION:
KS, OR, WA

Ship From:

KS

(b) (4)

Sedgwick County, KS, (b) (4), USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) KS (b) (7)(C), (b) (6), (b) (4) USA

OR

(b) (7)(C), (b) (6), (b) (4)

Morrow County, OR (b) (7)(C), (b) (6) USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) KS, (b) (7)(C), (b) (6), (b) (4) USA

(b) (7)(C), (b) (6), (b) (4)

Umatilla County, OR (b) (7)(C), (b) (6), (b) (4) USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) KS, (b) (7)(C), (b) (6), (b) (4) USA

CBI-DELETED

Monsanto Reference ID
2000-97XRAB

WA

(b) (4) Whittman County, WA, USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) WA, USA (b) (7)(C), (b) (6), (b) (4)

(b) (4) Lincoln County, WA, (b) (4) USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) KS, (b) (7)(C), (b) (6), (b) (4) USA

(b) (4) Benton County, WA, (b) (4) USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) WA, (b) (7)(C), (b) (6), (b) (4) USA, (b) (7)(C), (b) (6), (b) (4)

Ship To:

KS

(b) (4) Sedgwick County, KS, (b) (4), USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) KS, (b) (7)(C), (b) (6), (b) (4) USA

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Monsanto Reference ID
2000-97XRAB

OR

(b) (7)(C), (b) (6), (b) (4)

orrow County, OR (b) (7)(C), (b) (6), (b) (4) USA

CONTACT:

(b) (7)(C), (b) (6), (b) (4)

KS (b) (7)(C), (b) (6), (b) (4) USA

(b) (7)(C), (b) (6), (b) (4)

Umatilla County, OR (b) (7)(C), (b) (6), (b) (4) USA

CONTACT:

(b) (7)(C), (b) (6), (b) (4)

KS (b) (7)(C), (b) (6), (b) (4) USA

WA

(b) (4)

Whittman County, WA, USA

CONTACT:

(b) (7)(C), (b) (6), (b) (4)

WA, USA (b) (7)(C), (b) (6), (b) (4)

(b) (4)

Lincoln County, WA, (b) (4) USA

CONTACT:

(b) (7)(C), (b) (6), (b) (4)

KS (b) (7)(C), (b) (6), (b) (4) USA

CBI-DELETED

Monsanto Reference ID
2000-97XRAB

(b) (4) Benton County, WA, (b) (4) USA

CONTACT: (b) (7)(C), (b) (6), (b) (4) WA, (b) (7)(C), (b) (6), (b) (4) JSA, (b) (7)(C), (b) (6), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-97XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OR (2), WA (2)

OR

(b) (7)(C), (b) (6), (b) (4)

Morrow County, OR, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (7)(C), (b) (6), (b) (4)
USA, (b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4)

Umatilla County, OR, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (7)(C), (b) (6), (b) (4)
USA, (b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4)

WA

(b) (7)(C), (b) (6), (b) (4)

WA

(b) (4)

Lincoln County, WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (7)(C), (b) (6), (b) (4)
USA, (b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4)

WA

(b) (7)(C), (b) (6), (b) (4)

(b) (4)

Whitman County, WA, USA, 5 acres.

CBI-DELETED

Monsanto Reference ID
2000-97XRAB

RESPONSIBLE PERSON/RESEARCHER:
USA, (b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4) WA, (b) (7)(C), (b) (6), (b) (4)

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-97XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (7)(C), (b) (6)

Monsanto Company

February 08, 2000

OR120018_BR_005021

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 10, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-040-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-09n	Applicant #:	2000-97XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS OR WA		
Release destination:	OR WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005022

file copy

Mr. John Griesbach
Oregon Department of Agriculture
Plant Division
635 Capitol St., N.E.
Salem, OR 97310-0110

February 10, 2000

Dear Mr. Griesbach:

Enclosed is notification 00-040-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-09n	Applicant #:	2000-97XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS OR WA		
Release destination:	OR WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005023

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 10, 2000

Dear Mr. Wessels:

Enclosed is notification 00-040-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-09n	Applicant #:	2000-97XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS OR WA		
Release destination:	OR WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005024



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281



February 10, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-040-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-09n	Applicant #:	2000-97XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS OR WA		
Release destination:	OR WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (7)(C), (b) (6)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

 State concurs with APHIS determination.

*State cannot evaluate
provided information*

 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas Sim IV

Signature: (b) (7)(C), (b) (6)

Date: 2/24/00

State: Kansas

Rptloc01/R4



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OR120018_BR_005025



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Postit Date # of pages
Fax Note 3/10 3
To Diane Hatmaker
Fax# 301-734-8910
From Dan Hilburn
Phone# 503-986-4663

February 10, 2000

Mr. John Griesbach
Oregon Department of Agriculture
Plant Division
635 Capitol St., N.E.
Salem, OR 97310-0110

Dear Mr. Griesbach:

Enclosed is notification 00-040-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-09n	Applicant #:	2000-97XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS OR WA		
Release destination:	OR WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (7)(C), (b) (6)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kathleen J. R. Johnson

Signature: (b) (7)(C), (b) (6)

Date: 3-10-2000

State: Oregon

Rpt10c01/R4

MAR 13 2000



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OR120018_BR_005026



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 10, 2000

Dear Mr. Wessels:

Enclosed is notification 00-040-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-09n	Applicant #:	2000-97XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS OR WA		
Release destination:	OR WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (7)(C), (b) (6)

E. Dianne Halmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature

(b) (7)(C), (b) (6)

Date: 2/15/00

State: WA

Rptloc01/R4



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An Equal Opportunity Employer

FEB 15 2000

OR120018_BR_005027

March 15, 2000

(b) (7)(C), (b) (6)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (7)(C), (b) (6)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 15, 2000.

Interstate movement and Release
Notification no. 00-040-09n (2000-97XRAB)
Regulated article - Wheat
Destinations - Kansas, Oregon, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
J. Griesbach, Oregon Dept. of Agric., Salem, OR
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO

File number 00-040-09n

OR120018_BR_005028

Confirmation Report-Memory Send

Time : Mar-15-00 04:57pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 002
Date : Mar-15 04:56pm
To : 916367377085
Document Pages : 01
Start time : Mar-15 04:56pm
End time : Mar-15 04:57pm
Pages sent : 01
Job number : 002

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 15, 2000

(b) (7)(C), (b) (6)
Monsanto Company
700 Chesterfield Pkwy W
St. Louis, MO 63198

Dear (b) (7)(C), (b) (6)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 15, 2000.

Interstate Movement and Release
Notification no. 00-040-09n (2000-97KRAB)
Regulated article - Wheat
Destinations - Kansas, Oregon, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (7)(C), (b) (6)

E. Diane Harrison
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

CC:
T. Sim, Kansas State Board of Agric., Topeka, KS
J. Griesbach, Oregon Dept. of Agric., Salem, OR
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO



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OR120018_BR_005029

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

March 31, 2000

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms Hatmaker;

In reviewing Monsanto wheat notification, it was discovered a release site was inadvertently omitted USDA number 00-040-09n, Monsanto number 2000-97XRAB. The omitted site address is (b) (7)(C), (b) (6)

(b) (7)(C), (b) (6) Whitman
County, WA.

I apologize for any inconvenience this may cause. Please call me at 636/737-6032 if you have any questions.

Sincerely,

(b) (7)(C), (b) (6)

cc: (b) (7)(C), (b) (6), (b) (4) WA
R. Stokes, Regional Biotechnologist, Sacramento, CA

OR120018_BR_005030

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700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

July 25, 2000

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

The following wheat sites for release have been canceled.

USDA # 00-040-09n, Monsanto # 2000-97XRAB

(b) (7)(C), (b) (6), (b) (4)

Heppner Morrow County, OR

(b) (4)

Lincoln County, OR

USDA # 00-059-03n, Monsanto # 2000-182XRAB

(b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4)

Thompson County, (b) (7)(C), (b) (6), (b) (4) ND

(b) (7)(C), (b) (6), (b) (4) Trail County ND

USDA # 00-054-06n, Monsanto # 2000-170XRAB

(b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4) Cass County ND

USDA # 00-054-09n, Monsanto # 2000-174XRAB

(b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4) Galletin County, MT

USDA # 00-059-07n, Monsanto # 2000-188XRAB

(b) (4)
(b) (4) Minndoka County, ID

(b) (4)
(b) (4) Canyon County ID

If you need further information, please contact me at 636/737-6032.

OR120018_BR_005031

ajb
7/27/2000

MONSANTO

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Sincerely,

(b) (7)(C), (b) (6), (b) (4)

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

cc J. Griesbach, Oregon Dept. of Agriculture, Salem, OR
D. Nelson, North Dakota Dept. of Agriculture, Bismarck, ND
E. Gingerly, Montana Dept. of Agriculture, Helena, MT
F. Vega, Idaho Dept. of Agriculture, Boise, ID
R. Stoaks, USDA, APHIS, Sacramento, CA

OR120018_BR_005032

2000 Wheat Field Trial Report
USDA # 00-040-09n Monsanto # 2000-97XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Morrow	OR (NOT PLANTED)
Site 2	Umatilla	OR
Site 3	Lincoln	WA (NOT PLANTED)
Site 4	Whitman	WA

Umatilla County, WA – Site 2

(b) (4)

Whitman County, WA - Site 4

(b) (4)

(b) (4)

Whitman County, WA - Site 4

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2000 Wheat Field Trial Report
USDA # 00-040-09n Monsanto # 2000-97XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Morrow	OR (NOT PLANTED)
Site 2	Umatilla	OR
Site 3	Lincoln	WA (NOT PLANTED)
Site 4	Whitman	WA

Umatilla County, WA – Site 2

Planting Date: April 5, 2000

Destruct/Harvest Date: July 28, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Whitman County, WA – Site 4

Planting Date: April 3, 2000

Destruct Date: June 21, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Whitman County, WA – Site 4

Planting Date: April 11, 2000

Harvest Date: August 17, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

2/10/00 12:17 pm

Notification Tracking Sheet

=====
Bp number: 00-040-11n
=====

App number: 2000-102XRAB
Received: 2/09/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/10/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/08/00
End movement: 2/07/01
Begin release: 2/08/00
End release: 2/07/01
Acre: 5.00
CBI status: CBI
Fax: 636-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[<i>ajd</i>]	[2/10/2000]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[<i>SMK</i>]*	[2/11/2000]*
3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i>	[<i>KLW</i>]	[2/14/00]*
4. <input type="checkbox"/> State response		

O/d	Loc	Site	Reg
Interstate	*Dest*	KS	* *SCR *
Interstate	*Dest*	ND	* *SCR *
Interstate	*Orig*	KS	* *SCR *
Interstate	*Orig*	ND	* *SCR *
Release	*	*ND	* 1*SCR *

5. <input type="checkbox"/> Enter genes into database	[]	[]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw	[<i>KLW</i>]	[3/9/00]*
7. <input checked="" type="checkbox"/> Enter final data into database	[<i>KLW</i>]	[3/10/00]

Asked
Priscilla
to correct
the M1
terminator
description

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-102XRAB

Permit Unit

February 08, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-040-11n

1. USDA Reference Number

2. Applicant Reference Number 2000-102XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EEmail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-102XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4) (h) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b) (4) (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2000-102XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 -- [

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-102XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

ship up to 800 pounds of wheat seed to and from each location.

ORIGIN:
KS, ND

DESTINATION:
KS, ND

Ship From:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT: Brian Jenks, Monsanto Co, 5912 N. Meridian, Wichita, KS, 67204, USA, 701/857-7677

ND

(b) (4)

Ward County, ND, (b) (4)

CONTACT: Brian Jenks, North Central Research Experim, 5600 Highway 83 South, Minot, ND, 58701, 701/857-7677

Ship To:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID
2000-102XRAB

CONTACT: Brian Jenks, Monsanto Co, 5912 N. Meridian, Wichita, KS, 67204, USA, 701/857-7677

ND

(b) (4)

Ward County, ND, (b) (4)

CONTACT: Brian Jenks, North Central Research Experiment, 5600 Highway 83 South, Minot, ND, 58701, 701/857-7677

CONFIDENTIAL

Monsanto Reference ID
2000-102XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

(b) (4)

Ward County, ND, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: Brian Jenks, North Central Research Experim, 5600
Highway 83 South, Minot, ND, 58701, 701/857-7677

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-102XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 08, 2000

OR120018_BR_005046

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create

essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be

able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-102XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 08, 2000

00-040-11n

1. USDA Reference Number

2. Applicant Reference Number 2000-102XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-102XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-102XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID
2000-102XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

ship up to 800 pounds of wheat seed to and from each location.

ORIGIN:
KS, ND

DESTINATION:
KS, ND

Ship From:

KS

(b) (4) Sedgwick County, KS (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

KS, (b) (6), (b) (7)(C), (b) (4)

USA, (b) (6), (b) (7)(C), (b) (4)

ND

(b) (4)

Nard County, ND, (b) (4)

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

ND,

Ship To:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CBI-DELETED

Monsanto Reference ID

2000-102XRAB

CONTACT: (b) (6), (b) (7)(C), (b) (4) KS (b) (6), (b) (7)(C), (b) (4) USA (b) (6), (b) (7)(C), (b) (4)

ND

REDACTED

Ward County, ND, REDACTED

CONTACT: (b) (6), (b) (7)(C), (b) (4) (b) (6), (b) (7)(C), (b) (4) ND,

CBI-DELETED

Monsanto Reference ID
2000-102XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

(b) (4)

Ward County, ND, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4) ND (b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-102XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 08, 2000

OR120018_BR_005057

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-102XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 08, 2000

00-040-11n

1. USDA Reference Number

2. Applicant Reference Number 2000-102XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-102XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-102XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID
2000-102XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

ship up to 800 pounds of wheat seed to and from each location.

ORIGIN:
KS, ND

DESTINATION:
KS, ND

Ship From:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

KS,

(b) (6), (b) (7)(C)

USA,

(b) (6), (b) (7)(C), (b) (4)

ND

(b) (4)

Ward County, ND (b) (4)

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

ND,

Ship To:

KS

(b) (4)

Sedgwick County, KS (b) (4) USA

CBI-DELETED

Monsanto Reference ID

2000-102XRAB

CONTACT

(b) (6), (b) (7)(C), (b) (4)

KS

USA,

(b) (6), (b) (7)(C), (b) (4)

ND

(b) (4)

ND, (b) (4)

CONTACT

(b) (6), (b) (7)(C), (b) (4)

ND,

(b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-102XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

(b) (4)

Ward County, ND, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4) ND (b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

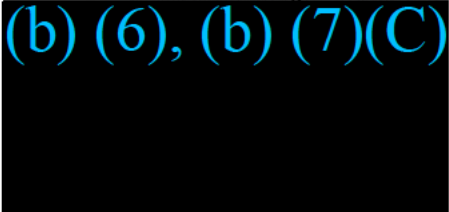
Monsanto Reference ID

2000-102XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 08, 2000

OR120018_BR_005064

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 10, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-040-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-11n	Applicant #:	2000-102XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005065

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 10, 2000

Dear Mr. Nelson:

Enclosed is notification 00-040-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-11n	Applicant #:	2000-102XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005066



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281



February 10, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-040-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-11n	Applicant #:	2000-102XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

*State cannot evaluate
information provided.*

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 2/24/00

State: Kansas

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_005067



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 10, 2000

Dear Mr. Nelson:

Enclosed is notification 00-040-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-11n	Applicant #:	2000-102XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: DAVID R NELSON

Signature: (b) (6), (b) (7)(C)

Date: 2-16-00

State: ND

Rpt10c01/R4



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An Equal Opportunity Employer

FEB 16 2000

OR120018_BR_005068

March 9, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 10, 2000.

Interstate movement and Release
Notification no. 00-040-11n (2000-102XRAB)
Regulated article - Wheat
Destinations - Kansas, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-040-11n

OR120018_BR_005069

Confirmation Report-Memory Send

Time : Mar-09-00 02:47pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 813
Date : Mar-09 02:42pm
To : 916367377085
Document Pages : 01
Start time : Mar-09 02:42pm
End time : Mar-09 02:46pm
Pages sent : 01
Job number : 813

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 9, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 10, 2000.

Interstate movement and Release
Notification no. 00-040-11a (2000-102XPAB)
Regulated article - Wheat
Destinations - Kansas, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Diagne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_005070

2000 Wheat Field Trial Report
USDA # 00-040-11n Monsanto # 2000-102XRAB

Biotech Field Compliance Team
June 15, 2001
Monsanto Company

Location
Site 1

County
Ward

State
ND

Ward County, ND- Site 1

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Cirtical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2000 Wheat Field Trial Report
USDA # 00-040-11n Monsanto # 2000-102XRAB

Biotech Field Compliance Team
June 15, 2001
Monsanto Company

Location	County	State
Site 1	Ward	ND

Ward County, ND- Site 1

Planting Date: May 23, 2000

Destruct Date: August 2, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

General Results of Trial: [CBI deleted]

2000 Wheat Field Trial Report
USDA # 00-059-01n Monsanto # 2000-179XRAB

Biotech Field Compliance Team
July 11, 2001
Monsanto Company

Location	County	State
Site 1	Cass	ND
Site 2	Cass	ND

Cass County, ND Site 1

(b) (4)

Cass County, ND –Site 1

(b) (4)

(b) (4)

Cass County, ND - Site 2

(b) (4)

Cass County, ND Site 2

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Citric Acid v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

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2000 Wheat Field Trial Report
USDA # 00-059-01n Monsanto # 2000-179XRAB

Biotech Field Compliance Team
July 11, 2001
Monsanto Company

Location	County	State
Site 1	Cass	ND
Site 2	Cass	ND

Cass County, ND Site 1

Planting Date: May 10, 2000

Destruct Date: July 21, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Cass County, ND –Site 1

Planting Date: May 8, 2000

Destruct Date: July 21, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Cass County, ND –Site 2

Planting Date: May 12, 2000

Harvest Date: August 15, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Cass County, ND Site 2

Planting Date: May 9, 2000

Destruct Date: August 24, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10 line 33391

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]